IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RJ REYNOLDS TOBACCO COMPANY, et al.,	)(	CIVIL ACTION NO. 6:20-cv-00176-JCB
PLAINTIFFS,	)(	
versus	)(	
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*;	)(	TYLER, TEXAS DECEMBER 11, 2020
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;	)(	TELEPHONIC HEARING
STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration; and	)(	
ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services;	)(	
DEFENDANTS.	)(	

TRANSCRIPT OF PROCEEDINGS
TELEPHONIC HEARING - MORNING SESSION
BEFORE THE HONORABLE JUDGE J. CAMPBELL BARKER
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

TYLER, TEXAS; FRIDAY, DECEMBER 11, 2020

MORNING SESSION

THE COURT: Good morning. This is Judge Barker, and we are here for a telephonic hearing on the motions for summary judgment and a motion for preliminary injunction in Case Number 6:20-cv-176, RJ Reynolds Tobacco Company, et al., versus the United States Food and Drug Administration, et al.

09:01AM

Will counsel for the parties please announce yourselves.

MR. WATSON: Good morning, Your Honor. This is Ryan Watson. I represent plaintiff RJ Reynolds Tobacco Company, Santa Fe Natural Tobacco Company, and the retailer plaintiffs. And I will be arguing today on behalf of the plaintiffs.

09:02AM

MR. BAER: Good morning.

MR. PERRY: Good morning, Your Honor. This is Phil Perry for ITG brands.

09:02AM

MS. KASCHEL: Good morning, Your Honor. This is Nancy Kaschel representing --

[INAUDIBLE]

THE COURT: I'm sorry. The last person who spoke, on my end, at least, your line was choppy. Could you repeat yourself?

09:02AM

[INAUDIBLE]

THE COURT: Well, may I ask: Can the court reporter hear all of the parties?

09:02AM

[STENOGRAPHIC COURT REPORTER CLARIFICATION]

THE COURT: It seems like we have a technical issue with the last speaker. I'm unable to hear you as well.

Would you try one more time to make your appearance.

09:03AM MS. KASCHEL: Your Honor, this is Nancy Kaschel for Liggett.

THE COURT: Very good. Now I can hear you.

And the court reporter?

[STENOGRAPHIC COURT REPORTER CLARIFICATION]

09:03AM THE COURT: Very good.

And for the defendants.

MR. BAER: Good morning, Your Honor. This is Michael Baer from the Department of Justice on behalf of the defendants. And I'm joined on the public line by my colleagues 09:03AM Stephen Pezzi and Eric Beckenhauer from the Department of Justice, along with colleagues from the Food and Drug Administration.

THE COURT: Very good. Thank you.

I assume that that completes all parties, outside of 09:03AM court personnel, who are on the speaking line. But if there's anyone else on the speaking line besides court personnel, please announce yourself now.

[NO RESPONSE]

THE COURT: Very good. Hearing no one.

09:04AM Let me walk through a few more preliminaries -- and

confirm that the court reporter could hear all of the counsel who just announced their appearance?

[STENOGRAPHIC COURT REPORTER CLARIFICATION]

THE COURT: Let me remind everyone of a few protocols to make today's hearing go smoothly.

Thank you for your accommodation of participation by telephone during the Coronavirus pandemic.

We should all be sure to take care to speak slowly and clearly so that we can all be heard by each other and by the court reporter during today's hearing.

To please mute your line when you are not speaking to reduce any background noise or feedback and to avoid speaking over each other when at all possible.

And, in general, at least during the first part of the hearing, to please announce your name before you speak, for the benefit of the court reporter and myself and anyone else listening who might not be readily familiar with each of your voices.

I detailed some more hearing protocols in my order setting this hearing. Please adhere to those as well.

Let me start with a few ground-clearing questions. I understand that plaintiffs have moved for a preliminary injunction; and that their complaint, of course, seeks a permanent injunction. We have now arrived at the point of complete briefing on cross-motions for summary judgment on the

request for declaratory relief and a permanent injunction, so I want to spend a minute asking about the necessity to engage with the preliminary injunction standards at this point, or whether both parties agree that the merits of the case can be fully resolved on the cross-motions for summary judgment.

09:06AM

As you recall, I did grant the parties' joint request to dispense with a statement in their summary judgment motions of any genuine issues of material fact because the parties agreed the case could be resolved on the cross-motions for summary judgment on the administrative record alone. I want to make sure that that is still the parties' agreement.

09:06AM

So on behalf of the plaintiffs, Mr. Watson, do the plaintiffs agree that there are no genuine issues of material fact to be resolved before the Court can decide the merits of this matter, either way?

09:06AM

MR. WATSON: Thank you, Your Honor.

We continue to agree that this case can be resolved as a legal matter the judicial review testing whether the agency action is consistent with law, and that does include the assessment of the certain issues in the administrative record under the Fifth Circuit precedent that is appropriately handled at summary judgment as a legal matter.

09:07AM

THE COURT: So do plaintiffs agree that at this juncture, now that we have the cross-motions and administrative record, the Court's focus should be on the merits of the

09:07AM

challenges, and, of course, any standards for permanent injunctive relief, as opposed to preliminary injunctive relief? In other words, do you agree that we've moved past the need to assess the preliminary injunction standard specifically?

09:07AM MR. WATSON: Thank you, Your Honor. This is Mr. Watson again.

And as to that question, I do know both the preliminary injunction and cross-motions for summary judgment are fully briefed, and we are continuing to seek a preliminary injunction 09:07AM which would enjoin the rule until 15 months after the plaintiff's claims are resolved on the merits. I'm happy to discuss why that is the case, but we are continuing to seek that relief.

It certainly is within the Court's discretion to proceed 09:08AM directly to the summary judgment motions and to resolve the case on that basis now. It also would be within the Court's discretion to issue a preliminary injunction relatively on the sooner side and then take longer to issue a summary judgment decision.

09:08AM THE COURT: Fair enough. I do think I understand what you're saying there.

Let me ask for the defendants to respond, to make sure I understand the parties' views on the procedural posture. Do the defendants still agree, as they did when they filed the 09:08AM joint motion to excuse any statement of genuine issues of

material fact, do the defendants still agree that there are no genuine issues of material fact to be resolved before the Court can resolve the merits of this matter, one way or another, on the cross-motions for summary judgment?

09:09AM MR. BAER: Yes, Your Honor. Defendants agree with that, and they agree that this case raises purely legal questions by virtue of its posture arising on the basis of an administrative record. And we, therefore, agree that it is appropriate for the Court to proceed directly to the merits and to the

09:09AM resolution of the cross-motions for summary judgment.

THE COURT: Very good. Thank you.

And one more ground-clearing question. This is for the plaintiffs, and this is with respect to your statement, Mr. Watson, about your request for injunctive relief that would

09:09AM last for some period of time, independent of the Court's ruling on the merits.

Given the Court's recent order extending the stay of the agency's rule's effectiveness, when would the plaintiffs again face imminent compliance cost that will prompt them, if there

09:10AM is no merits ruling at that point and no injunction, that would prompt the plaintiffs to seek another stay of the rule's effectiveness?

MR. WATSON: Your Honor, I believe that that would be approximately March of 2021, which is 90 days after the date

09:10AM that I had given you when we had the status conference a few

weeks ago, at which point I picked that time period as December 2020. So, essentially, 90 days out from what we discussed the last time.

THE COURT: All right.

09:10AM So, if by March of 2021, the Court were able to rule on the merits of the challenges in the summary judgment posture, then at that point, however the Court ruled, that would moot your request for a preliminary injunction; correct?

To spell that out and unwind it a little bit, assuming, 09:11AM arguendo, the Court order rules for plaintiffs, you would at that point have been requesting a declaration and a permanent injunction, as opposed to a preliminary injunction. And assuming, arguendo, that the Court were to rule for defendants, then, necessarily, the request for a preliminary injunction 09:11AM would be overtaken by events, because on that hypothetical outcome there would be no likelihood of success for the plaintiffs.

So to abstract my question again, if the Court were able to rule by March of 2021 on summary judgment, fully resolving 09:11AM the merits, one way or the other, that would simply moot the necessity to engage with the elements for a preliminary injunction; am I understanding that correctly, Mr. Watson?

MR. WATSON: Yes. That is absolutely my understanding, based on the facts as they currently stand. And at that point, 09:12AM the injunctive relief that we would be seeking is a permanent

injunction that enjoins the rule until 15 months after the claims are resolved.

THE COURT: Very good.

Mr. Baer, am I understanding that procedural posture of the case correctly in your view as well?

MR. BAER: Yes, Your Honor.

And I would just note for the record that, of course, all of these considerations are contingent upon a finding that venue is appropriate in this district. I don't intend to bring up the venue issue at any other point in this morning's argument. But I would just note that we're proceeding, assuming, arguendo, that the Court were to deny the defendant's pending motion to dismiss; or, in the alternative, transfer venue.

THE COURT: Very well. So noted.

Let me move on then to the merits of the competing motions for summary judgment. Let me start with the plaintiffs.

I'm not going to set a firm time limit, but I will ask you to give, essentially, your opening argument, and then I will jump in with questions as appropriate. If could you start with your First Amendment challenge, please.

MR. WATSON: Yes. Thank you, Your Honor. And may it please the Court.

As the briefs explained, the rule is invalid in its

entirety because it violates the First Amendment in unprecedented and egregious ways. The government seeks to require exaggerated warnings that feature large and grotesque images to be included on cigarette packs and advertisements. Never before in American history has such warnings been upheld. And, indeed, the only time the government tried -- which was in the FDA's 2011 Graphic Warnings Rule -- the Court held that they were unconstitutional. Likewise, here, the government has again failed to justify this extraordinary imposition on plaintiff's speech.

09:13AM

09:13AM

First, the government does not claim that the warnings will have any real-world impact. Indeed, its own data from the previous rule and the record evidence relating to this rule show that the warnings would not have any impact on smoking rates. Instead, we only --

09:14AM

THE COURT: Mr. Watson, let me stop you there. The government argued that the real-world impact that the warnings would have is heightened consumer education either of the risk in general or of the specific risk of smoking tobacco cigarettes. Can you respond why that is not a sufficient real-world in that?

09:14AM

MR. WATSON: Because in this case, Your Honor, the real-world impact in terms of affecting smoking rates is something that FDA tried to prove last time and failed, and admittedly failed, and the Court held that it had failed. And

09:14AM

this time the FDA is not even attempting to do that. So it's an academic interest in conveying certain information for the sake of information, while we know that the government doesn't even claim that it will affect smoke rates, and there's
09:15AM evidence in the administrative record demonstrating that it will not, in fact, affect smoking rates.

THE COURT: Now, the statute itself, the Tobacco Control Act, doesn't that tag the agency's ability to act to findings that certain changes to the labeling would better promote
09:15AM public understanding of the health and safety risks of smoking, and isn't that enough to show that at least Congress thought that better consumer understanding was a tangible real-world outcome?

MR. WATSON: Your Honor is correct, that the statutory
09:15AM provision relating to the changes to textural warnings does refer to that. But as the DC Circuit found in the *RJ Reynolds* case in 2012, and as the *Cigar Association* case from the DC Circuit this year again emphasized, the purpose that Congress had for the statute is to reduce smoking rates. And, here,
09:16AM that's something that the government did not even consider, how its warnings would affect smoking rates, and conceivably cannot demonstrate that, and it is our contention that that is the interest that Congress envisioned and that FDA could be pursuing but for the fact that they cannot demonstrate it. The
09:16AM informational interest that they have asserted here, in our

view, is not constitutionally sufficient.

And I think it is worth just refining the particular informational interest that is being asserted here. FDA is not claiming that the rule will impact smoking rates, for which we just discussed. It's also not claiming that the rule is intended to increase knowledge about the general harms of smoking or that it is intended to communicate absolute relative or dose response risk of smoking. Instead, it is asserting an interest in promoting understanding of the specific granular consequences that are depicted in these particular graphic warnings.

09:16AM

09:17AM

THE COURT: Well, this is a little more abstract than the point you were making, but let me ask you about the government's interest in preventing consumer deception. Do you agree that that would qualify as a substantial interest under the *Zauderer* test?

09:17AM

MR. WATSON: We do agree that that would qualify as an appropriate interest under the *Zauderer* framework. And, indeed, that is the only interest, in our view, that can be asserted under the *Zauderer* framework. And if the government cannot show that that interest is applicable here -- which, in our view, it can't -- then *Zauderer* is categorically inapplicable.

09:17AM

THE COURT: My next question then is: Do you agree that reducing or eliminating consumer deception is simply one

09:18AM

species of promoting consumer understanding? That those are just two sides of the same coin?

MR. WATSON: No. We think that those are two different interests, and I'm happy to explain why.

09:18AM When the Supreme Court in *Zauderer* itself was addressing the interest in preventing consumer deception, and the other cases as well, including *Test Masters* and *Milavetz*, these are all situations where the commercial speech at issue was deceptive or potentially misleading, and the compelled

09:18AM disclosure was going to remedy the deception that appeared in that particular advertisement or that particular piece of commercial speech at issue.

So in the *Zauderer* case, for example, the attorney wanted to run an advertisement seeking prospective plaintiffs

09:19AM and telling them that if they lost the case they would not have any financial responsibility. That was potentially misleading because he did, in fact, plan to charge them for the costs but not the fees of the case, and, thus, the disclosure that was being compelled remedied that potential confusion.

09:19AM So the preventing consumer deception rationale that is applicable under *Zauderer* is not a free-floating consumer deception rationale, but, rather, it is tied specifically to correcting the potentially misleading issue that is created by the commercial speech in that instance.

09:19AM THE COURT: Can the government act under *Zauderer* to

remedy potential consumer deception that arises from a shared public understanding or past disinformation campaigns?

MR. WATSON: As to past disinformation campaigns, just as an initial matter, we do not agree that we made misrepresentations historically, and the administrative record does not directly address that issue.

But, here, it is established as a matter of the record that the public knows that cigarettes are harmful, and the government has not shown that the public remains mislead about any alleged misrepresentations, let alone any misrepresentations about these particular issues that are being discussed in these warnings.

I would also note on the historical alleged misrepresentations point that the retailer plaintiffs conceivably have not made any misrepresentations, and so that rationale would not even apply to all of the plaintiffs in this case.

And again, we contend that the *Zauderer* standard does not encompass that situation because *Zauderer* is limited to correcting the deception in the particular speech at issue, and it's undisputed that the current advertising and its packages are not misleading, and that's not the basis upon which this rule was issued. And, in fact, the Tobacco Control Act separately prohibits any such misleading statement in the current packages and advertising.

THE COURT: And when you say that the FDA has not attempted to show that these warnings would lead to a reduction in smoking, your baseline for that is a reduction from current percentages of adults or people who smoke; correct?

09:22AM MR. WATSON: Correct.

THE COURT: What do you say to the defendant's suggestion that Congress's interest in reducing smoking rates, not from necessarily current levels but from what the rates would otherwise have been without any warnings at all?

09:22AM MR. WATSON: That notion, if embraced, would be inconsistent with the way that the First Amendment litigation proceeds. That it is the government's burden to demonstrate that the burden that it is imposing here, the compelled speech, is justified by the adequate type of interest and demonstrating

09:22AM that the rule would sufficiently and materially advance that interest without being unduly burdensome, that standard cannot be satisfied if it is being pegged to getting smoking rates to something better than they were at some point in the past. The First Amendment burden that this rule creates is being imposed

09:23AM now. Or, obviously, once the rule takes effect, it will be even more so. That burden, under the First Amendment standard, has to be weighed against any current benefits that the rule would deliver, not any notion that it is making things better than they were in the 1960s.

09:23AM THE COURT: I guess my question is more targeted just

based on what is a sufficient substantial interest if *Zauderer* did apply or under the *Zauderer* framework. Courts sometimes hold that the government doesn't have to tackle all aspects of the problem at once and can move incrementally.

09:23AM So it is your position that it would not be a substantial interest to reduce smoking rates from what they would otherwise be without any warnings; that we have to focus only on the specific incremental addition to the warnings that are at issue here?

09:24AM MR. WATSON: The baseline that this rule has to be evaluated against is the status quo as it currently exists, which involves the surgeon general's warnings that have been on the packs for a number of years. That is what they need to show that they are materially improving. And we would say they need to show they're materially improving by showing a reduction of smoking rates, not just some academic informational interest. But in any event, the baseline is the status quo as it currently stands.

The FDA is proposing to create a new and more onerous 09:24AM burden on the First Amendment going forward. And to justify that, they need to, among other things, show that they are going to materially advance a sufficient interest going forward, as measured against the current status quo with the current surgeon general warning.

09:25AM THE COURT: Staying on the framework question a little

bit before getting into some of the specifics of this rule, let me ask you to respond to the government's argument about the Sixth Circuit *Discount Tobacco* case. I have two questions about that.

09:25AM First, in *Discount Tobacco*, Judge Stranch suggested that the purely factual and non-controversial disclosure requirement was not a standalone requirement under *Zauderer*, but rather this language appears in *Zauderer* once, and the context of its appearance does not suggest that the Court was describing

09:25AM necessary characteristics of a disclosure.

Can I ask for the plaintiff's view on whether that is accurate or inaccurate.

MR. WATSON: To address the question specifically, and then maybe I'll circle back to *Discount Tobacco* a little bit

09:26AM more broadly. The way that we understand the purely factual inquiry to work is that that is a threshold requirement that must be satisfied in order to trigger *Zauderer* review. The case law is somewhat inconsistent on whether the purely factual element is a threshold requirement that must be satisfied to

09:26AM trigger *Zauderer* or whether it is, in fact, an element of the *Zauderer* test. And the government's opening brief framed it in the latter way, and ours framed it in the former way. But that's how we understand the purely factual element to work.

I would say that another important thing to understand

09:26AM about *Discount Tobacco* is that it was applying a now outdated

and abrogated standard under *Zauderer*. *Discount Tobacco* said that *Zauderer* was a, quote, rational basis standard. It has also specifically said that the court was not required to specifically analyze whether the warnings were unduly burdensome or unjustified. And as demonstrated by the *NIFLA* case from the Supreme Court last year, at pages 2,376 to 2,377, that is now an understanding of *Zauderer* that has been abrogated by the Supreme Court. And, thus, we think *Discount Tobacco*'s analysis has no real persuasive effect here.

09:27AM THE COURT: And the government also argued that, regardless of any persuasive effect, it has an issue preclusion effect as to RJ Reynolds because it was a party there. Would you briefly give your response to that argument.

MR. WATSON: Yes. I'd be happy to. And there are three 09:27AM main points I think that are important to understand in response to that question.

The first is that the government has forfeited any preclusion argument here because it raised this claim preclusion point with a one-sentence footnote, with no 09:28AM citations, and it never raised issue preclusion

Secondly, the parties in this case are not the same. Thus, preclusion doesn't apply.

So claim preclusion is limited to successive litigation, the very same claim by the same paries. *Whole Woman's Health* 09:28AM stands for that proposition. And a similar requirement applies

to issue preclusion under *Taylor versus Sturgell*.

Here, there are a number of plaintiffs that were not plaintiffs in the *Discount Tobacco* case, including Liggett, including the retailer plaintiffs. And, thus, even if the relevance claims were precluded -- which they are not -- the other claims would not be.

09:28AM

And then the third of the three points is that intervening factual and legal developments since *Discount Tobacco* make both claim preclusion and issue preclusion inapplicable even as to Reynolds.

09:29AM

As to the factual development, this is a situation like *Whole Woman's Health*, the Supreme Court decision, which said that when individuals claim that a particular statute is going to produce serious constitutional adverse consequences before they have actually occurred, and when the courts doubt that that's actually going to happen, the factual difference years later that those adverse consequences have, in fact, occurred can make all the difference; and, thus, claim preclusion doesn't apply in that situation.

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09:29AM

And so as to the intervening case law, it's the point that I just made a moment ago that *NIFLA* makes *Discount Tobacco* decision a relic and renders it an incorrect statement of the current First Amendment doctrine; and, thus, issue preclusion and claim preclusion are inapplicable.

09:30AM

I'm happy to give citations for the notion that claim

preclusion ask issue preclusion don't apply when there's an intervening change in law on a constitutional issue like this, but I'll stop and pause here to see whether that would be helpful to the Court.

09:30AM THE COURT: Well, I think maybe a better use of our time this morning would be for me to move on to questions about the rest of the First Amendment issue.

On the purely factual and uncontroversial prong of the *Zauderer* test, is plaintiff's position that -- let me ask it 09:30AM this way:

The government, I think at page 33 of their opposition, they argue that the plaintiffs do not disagree that the textual warnings in the agency rule are purely factual and uncontroversial, as opposed to text plus the graphics. Would 09:31AM you clarify your position on that proposition.

MR. WATSON: I would be happy to. And I will start by just saying: No, we do not agree with that statement, and I'm happy to elaborate on why.

There are actually several arguments that we have as to 09:31AM why the warnings here are not purely factual and are not uncontroversial.

THE COURT: And are you focusing just on the textual warnings?

MR. WATSON: I intend to, yes.

09:31AM THE COURT: Okay. Very good. Thank you.

Please proceed.

MR. WATSON: Okay. Yes.

So we do have some of those arguments that are focused on the images as well.

09:31AM But as to the textual warnings, there are a couple of things to note. One is that the warnings here are controversial because they are misleading and exaggerated. And under *RJR, American Meat Institute and Entertainment Software*, that renders warnings controversial. And, here, we contend --

09:32AM and we explain why the warnings, not just the images but also the text -- are misleading and exaggerated.

The government didn't even test whether the warnings conveyed accurate messages. But we fleshed out in our briefs at pages 26 to 27 of our opening motion and pages 13 to 15 of

09:32AM our reply of why each of the warnings is exaggerated. And some of those, to be sure, addressed images, but some were addressing factual points as well.

For example, the textual statement's use of causal language is misleading and subject to misinterpretation. They

09:32AM use -- many of them use the term "causes" rather than saying "may cause" or "can cause."

And the FDA's own first qualitative study found -- in fact, its most prevalent finding -- was that participants had a negative reaction to that, and that that was confusing, and

09:33AM they found that to be not credible.

Also, the warnings, many of them focus on less frequent negative health consequences and portray them as things that, although they are in fact rare, they portrayed them as things that would happen in the common case, and that is a problem that affects both images and text here.

09:33AM

One example of that is the cataracts warning which talks about blindness as a result of the cataracts, and the text is doing this as well as the image. In fact, blindness occurs in only 0.48 percent of US cataract patients, which is rare, but the warning is portraying it as common. And that's a specific thing that RJR found at page 16 to render the previous warning controversial. And we think all of the warnings here fall for the same reason.

09:33AM

Also, I would --

THE COURT: You do have a dispute as to the uncontroversial element regarding the meaning of causes in the textual warning. You're saying the degree of causation is not successfully high as to make that statement uncontroversial.

09:34AM

What do you do with the FDA's argument that all the textual warnings were selected as among highest level of causation in the surgeon general's study?

09:34AM

MR. WATSON: So the FDA makes that point; but it says -- inaccurately, in our view -- at page 6 of its reply brief, that the rule is using the same causal language as the surgeon general's reports. But that is not accurate. These warnings

09:34AM

don't use the careful surgeon general's report causal language, which is much more nuanced than what the warnings demonstrate here. I would cite to page 5,868 of the joint appendix for that point.

09:35AM And there is one place that's cited in the surgeon general's report that uses the word "causes" with respect to the diabetes warnings specifically, but it does that as sort of a shorthand, and it does it when referring the reader to another section of the surgeon general's report where it 09:35AM discusses more fully with precise causal language. And that's at Joint Appendix 6,381 and Joint Appendix 6386.

So that point is unpersuasive for various reasons, but the most fundamental one is the warnings here are not replicating the careful causal language that the surgeon 09:35AM general's report is using.

THE COURT: So your dispute with the accuracy of the causal link implied or suggested by the text on the warnings exists with how many of the textual warnings?

MR. WATSON: The majority of the warnings use "causes." 09:36AM I'm happy to run through each of them, but it is the majority of them.

THE COURT: You mentioned cataracts was one.

MR. WATSON: Cataracts is one that uses "causes." Head and neck cancers does as well. The "smoking reduces blood flow 09:36AM to the limbs" doesn't use the word "causes" but it uses the

word "reduces," which creates a similar use. Likewise, the erectile dysfunction uses "reduces" rather than "they reduce." The fatal lung disease in non-smokers uses the word "causes." COPD uses the word "causes." Bladder cancer uses the word "causes." Diabetes does as well. The "smoking during pregnancy" uses the word "stunts" rather than "may stunt." Cataracts, which we discussed. I think that's the end of that list.

09:37AM

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09:38AM

THE COURT: In the DC Circuit litigation, the court's 2012 panel opinion in the RJ Reynolds versus FDA litigation stated that, there, the companies who were parties in that litigation -- the quote from that opinion is: The companies do not dispute Congress's authority to require health warnings on cigarette packages, nor do they challenge the substance of any of the nine textual statements mandated by the act.

Now, of course, I appreciate that the textual statement at issue here varies in some regards with those mandated by the act, but some of the textual warnings at issue and addressed in that 2012 decision also used the word "cause." For instance, "cigarettes cause fatal lung disease," "cigarettes cause strokes and heart disease."

So let me ask you at least about RJ Reynolds, since it was a party in that litigation and is a party here: What has changed from that litigation, where there was no dispute with the substance of the textual statements, to the textual

statements at issue here?

MR. WATSON: So we are challenging these particular warnings on this particular record. But we're not saying that the content of the TPA specified warnings is necessarily unconstitutional in all possible future cases, in all possible factual records.

09:39AM

And, here, the important thing to distinguish is the factual record that we have here and the specific warnings that we have here. Only two of the warnings here are precisely the same text that's specified in the Tobacco Control Act, and, thus, the same text precisely that was at issue in the DC Circuit's decision. There's only two that overlap.

09:39AM

THE COURT: Which two are those, just for the purposes of clarifying our discussion today?

09:39AM

MR. WATSON: Yes. So the "tobacco smoke can harm your children" warning, and the "tobacco smoke causes fatal lung disease in non-smokers" are the only warnings where the text is exactly the same as the Tobacco Control Act warnings. So those are the only two.

09:40AM

THE COURT: Just a few moments ago, you gave the second warning, "tobacco smoke causes fatal lung disease in non-smokers" as an example of one where you do challenge the text as not satisfying the purely factual and uncontroversial *Zauderer* element. Correct?

09:40AM

MR. WATSON: Correct.

THE COURT: And, again, is that a different position than the position that at least RJ Reynolds took as reflected in the DC Circuit 2012 panel opinion, where it stated that: The companies do not, quote, challenge the substance of any of the nine textual statements mandated by the act, end quote?

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MR. WATSON: It is different in the sense that we are making that challenge here, whereas we were not making the challenge specifically to the text there. But it's not different in the sense of being inconsistent, because as I noted a moment ago one of the things that is different now is we have a different administrative record, and even the FDA's only study had the most prevalent finding being that "causes" is a problem.

09:40AM

And the "tobacco smoke causes fatal lung disease in non-smokers" text here is also combined with an image that is problematic for reasons I'm happy to discuss, and the FDA did not separately test its images and text as a combination as compared to just the text. It didn't separately test in that second quantitative study what it would be like to use the text compared to text plus images, and so the only evidence we have here that the FDA produced is the testing as to the text plus images. And that record evidence demonstrates that, for a host of reasons, that particular warning -- and, indeed, all of them -- are not purely factual and are not uncontroversial.

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THE COURT: So the plaintiffs do agree, however, that

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the controversial or uncontroversial prong of the *Zauderer* test refers to the factual accuracy of the statement, as opposed to whether the statement is disturbing. Correct?

MR. WATSON: So there's a couple of cases I would point the Court to as to how we understand the controversial prong, which includes the RJR decision which said that: Graphic warnings that are subjective and perhaps even ideological are controversial.

The *National Association of Manufacturing* case from the DC Circuit, at page 530, which said that: If information is intend to skew public debate or to stigmatize, then that's partly non-ideological and is, thus, controversial. And the *American Beef Institute* case from the en banc DC Circuit, which said that if it is too one-sided or if it conveys innuendo it is controversial.

So we do not think that the assessment of whether a warning is controversial is limited simply to the question of whether it is a medically accurate depiction of the particular consequence that is being described, but, rather, does include a consideration of the sources of the elements I just mentioned.

THE COURT: Right. But you do agree that there's some factual information -- factual as opposed to opinion, fact assertion of the real-world affect and not a norm -- there's some factual information that is accurate beyond reasonable

controversy but it's nonetheless disturbing to learn of just as a state of the way the world works. Sometimes we learn disturbing but uncontroversial facts; correct?

MR. WATSON: That is certainly true in terms of a statement of how the world works, but there's a difference between warnings that may elicit an emotional response from some segment of the population and warnings that are objectively designed to and, in fact, elicit an emotional and shock response from a significant number of those who view the warnings.

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And, here, FDA decided to not only use textual warnings, which have been demonstrated to be as effective, but to also include the disturbing and the shocking images.

THE COURT: Would you say, on behalf of plaintiffs, that a skull and crossbones image on poisonous chemicals is controversial because it's disturbing for some people? It's disturbing for some people to look at a skull and crossbones?

09:44AM

MR. WATSON: Although it would depend on the particular factual record at issue there, I think that adding a skull and crossbones graphic to the word "poison" might not add anything non-factual to the warning, and might help children or non-English speakers to understand the warning. So I think that it is possible that that is the sort of image that may survive First Amendment review.

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And, here, just thinking relevant to the particular

issue here, perhaps the government could use an image that depicts a warning written in handwriting, which might be more readable and easier to understand than printed text, without adding any elements that are not purely factual and uncontroversial.

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I would also note that, when thinking about the factual issue, the test is not whether there is some factual component in the warning, but rather the test is whether it is, quote, purely factual. Here, in our view, that is plainly not satisfied, for a host of reasons.

09:46AM

THE COURT: In the warning that indicates that "tobacco use can lead to death," instead of a picture that is in the rule here, would a picture of a skull and crossbones, with that textual warning, convert it from uncontroversial to controversial, in your view?

09:46AM

MR. WATSON: There are a host of sort of sub-elements to that question.

One is: I can't answer it in the abstract without knowing what the administrative record for such a warning would reveal. Certainly, skull and crossbones eliminates some of the problems we've identified here. But without -- again, it is the government's burden under the First Amendment to demonstrate all of these things; and without seeing the record and seeing whether they have carried that burden, I can't fully answer that question.

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But, yes, a skull and crossbones in general and in the abstract, I agree, could conceivably be the sort of thing that would not run afoul of our arguments, but it's going to depend on the details.

09:47AM Here, we have a study in the administrative record that shows that 86 percent of the respondents believe that the warnings are trying to make people feel afraid, and 85 percent believe that they are trying to shock people, and 75 percent of the smokers think that they're trying to convey the advocacy 09:47AM message that people should not smoke cigarettes. That is just one of many pieces of evidence in the record here that demonstrate that all of these warnings, both images and text, can't get over the purely factual and uncontroversial hurdle.

THE COURT: If the government does have the legally 09:47AM valid substantial interest under *Zauderer* or *Central Hudson* in increasing or even just maintaining consumer awareness of the health risks of smoking, at that point would you say that having graphics to ensure retention of the message is, nonetheless, not a sufficiently tailored fit for that interest?

09:48AM MR. WATSON: That's correct. Even if we assumed, arguendo, that the informational -- academic informational interests that the government is asserting here were substantial and, thus, constitutionally adequate for the purpose of this question, we would still contend that these 09:48AM warnings are unconstitutional, both because they're unjustified

-- they're not actually going to materially improve that interest -- and also because they are unduly burdensome, they are imposing too much of a burden that's broader than reasonably necessary. And under *NIFLA* that is enough -- even under the *Zauderer* standard -- to invalidate these warnings.

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I'm happy to elaborate and would enjoy the opportunity to elaborate on those, if the Court is interested.

THE COURT: Let me move to a little bit different prong of the test, which is how much time after a history of deceptive advertising is necessary before that history becomes too remote, in plaintiff's view?

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MR. WATSON: So, again, we don't think that *Zauderer* encompasses any attempts to correct an alleged historical misrepresentation. And the government has not made an argument based on the *Warner-Lambert* case based on the DC Circuit here, but that is a case that was cited in the amicus brief. And that's a case from 1977 that allowed, essentially, a corrective statement to remedy misleading advertising that had occurred in the past about Listerine.

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THE COURT: Yes, Listerine.

And in that case, did the court require the government to show that the corrective advertisement, stating that Listerine does not cure the cold, did the Court require the government to show that that advertisement would do anything more than promote accurate public understanding of the

09:50AM

properties of the product in question?

MR. WATSON: I believe that that case -- which, again, the government is not even invoking here -- was focused on correcting the deception that had happened in the past. But it's distinguishable because, unlike in that case, there's no specific deceptive claim here, either recent or otherwise, that the graphic warnings and their depiction of negative health consequences are targeted to address, nor is there any evidence that the public remains mislead or confused about any alleged prior deception. In fact, the public has been warned about the dangers of smoking on cigarette advertising since 1984 and on cigarette packages since the 1960s.

And we made detailed arguments about the state of public knowledge at this point in time in our briefing, and, indeed, that is one of the reasons why any informational interest at issue here, even if sufficient, in theory, would not actually materially improve the public's understanding of the risks of smoking. The public already understands the overall and major risks of smoking. And, indeed, FDA's own dataset shows that 99.5 percent of adult respondents believe that smoking is harmful to health, 94 percent believe it causes lung cancer in smokers, 88 percent believe it causes heart disease in smokers, et cetera.

And in addition to the knowledge that exists right now about the overall risks of smoking and the major risks of

smoking, which I was just discussing, many of the specific health consequences, the granular consequences that are being addressed in these particular warnings, are also well-known. And I'm happy to run through those as well. But all of that --

09:52AM THE COURT: Didn't the FDA also find in the record that the current textual warnings on the side of cigarette packages were failing to reach some consumers? Essentially, where they were just overlooked?

MR. WATSON: The FDA does state that the surgeon general 09:53AM warnings has become stale, and they may have used the word overlooked. But they did not -- and this is important to emphasize -- they did not test any less restrictive alternatives. For example, they did not test whether putting text just on the side of the package with new text would 09:53AM accomplish everything that they hoped to accomplish here without creating the larger First Amendment burden on the plaintiffs. And against that lack of evidence from the FDA, it had to be contrasted with the affirmative evidence that the plaintiffs put into the administrative record, which involves a 09:53AM study by Dr. Iyengar which showed very few statistically significant differences as to new information conveyed or beliefs about smoking risks, which he compared putting large graphic warnings on 50 percent of the top and the front and the back of the packages, as compared to putting less restrictive 09:54AM warnings on just the side of the package. And so the

government hasn't tested that, even though it has a constitutional duty to do that.

By contrast, we affirmatively -- even though it's not our burden -- we affirmatively put in the evidence that demonstrates that there are less restrictive alternatives that would have been, at least, as affective.

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And also, the surgeon general's warnings, which we're all familiar with, have worked well, so there's no reason to think that new textual warnings on the side of the pack couldn't work well again.

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One element of Your Honor's question mentioned reaching an adequate number of people, and I think that some of that discussion in the briefing comes up in the context of an informational campaign. Plaintiffs argue that one of the many less restrictive alternates that FDA needed to consider and should have pursued would be a public information campaign, which FDA is often using in the tobacco context and trumpets as wildly successful. But if the government intends to impose a novel unprecedented and highly burdensome graphic warnings requirement, it must at least demonstrate that it couldn't achieve those goals through its own speech, like an information campaign.

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And the government, in response to that, says: Well, we don't think that an information campaign would reach everybody who would look at a package of cigarettes; and in that sense

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it's not reaching enough people.

And in response to that, I would note, first of all, they cite zero evidence to support that. It's just a statement by counsel in the brief. And I would point the Court to the *NIFLA* case from the Supreme Court just last year, which, at page 2,376, invalidated the requirement largely because the state could have used a public information campaign, and it rejected -- the Supreme Court rejected the state's argument that the campaign was not effective, and it rejected that because the state gave no evidence that it was ineffective and because getting a tepid response in response to their campaign was not enough to make it constitutionally insufficient.

So I'll pause there, but I thought all of those were implicated by Your Honor's question.

THE COURT: Thank you.

Let me move from your narrow tailoring point, which I believe I understand, to, again, back to one final question, I think, on the purely factual and uncontroversial prong where the plaintiffs have argued that the emotional impression left by looking at the images is part of what makes them controversial, not uncontroversial, within the meaning of that test.

In her dissent in the 2012 DC Circuit opinion, Judge Rogers argued that that argument by the tobacco companies leads to the counterintuitive conclusion that the more severe the

negative health affects of a product the more constrained the government is in mandating disclosure of those risks because the public would be more alarmed at learning those risks. What is your response to that point?

09:57AM MR. WATSON: My response to that point is that I fundamentally disagree. For example, the surgeon general warnings that currently appear on cigarette packages are far more factual than what we're looking at here in this case. They address the same overall issue, which is what are the

09:58AM risks of smoking. And, indeed, there's evidence that they have helped to improve the way that cigarette smoking in this country -- those are examples of warnings about smoking risks that seem to have worked. Just because it involves cigarette smoking and serious issues doesn't mean that the government

09:58AM cannot appropriately craft a warning that is purely factual; it just means that they need to actually try to create a warning that is not emotional and shocking and ideological.

And, here, they clearly did not try to do that. And, in fact, there's evidence that they repeatedly revised the images

09:58AM to make them more frightening and more grotesque.

It is possible that the government could create new warnings that may be purely factual, but they have not done so here. And FDA's own qualitative studies show this. People are reacting to them, saying these are insanely graphic and scare

09:59AM tactics. In fact, a number of these images are mere parallels

to what was in the 2011 rule. So there are just all sorts of reasons why these ones can't get over the threshold of being purely factual.

But I do not agree that it is ham-stringing the government's ability to create warnings about smoking. It just means that they need to be careful, and they need to comply with the First Amendment and assemble the adequate First Amendment record, and none of that has been done here.

And, in fact, here, one of the problems -- which we haven't touched on yet -- is that these sort of realistic images are inherently subject to multiple interpretations, which prevents them from being purely factual. And the government has the burden to show that they actually are conveying solely and unambiguous factually correct meanings, and it hasn't done that, and hasn't even really attempted to do that.

Which is why you have people looking, for example, at the erectile dysfunction warning in the qualitative study and saying: I think this might be about a strained relationship, or infertility, or insomnia, sleeplessness, stress or depression. People are confused and they don't understand what message is even being conveyed. Both the qualitative and quantitative studies demonstrate that, and that is yet another reason why these warnings are not purely factual.

But, of course --

THE COURT: Does the government have a substantial interest in including graphics that help communicate the point of a textual warning to those who speak any of the many different languages spoken in our country?

10:01AM MR. WATSON: We disagree at the threshold that the government has a substantial interest in promulgating warnings that are trying to convey these granular specific consequences of smoking in the first instance.

The government does point to the point that Your Honor 10:01AM just made. But the fact that -- so what the government says is whatever problems are created by the images are fixed by the text. And I think that's an inconsistency in the government's position, because they elsewhere make the point you just made, which is that although the graphics help people who can't read 10:01AM the warnings very well. But both of those things can't be true. And if the warnings images have a problem and the text is supposed to fix them, how does that work with respect to people that can't read the textual warnings? So I think there's just a cognitive difference in some of those positions 10:02AM on the government's part.

THE COURT: Right.

One more question, just on the legal framework here. To confirm my understanding that, on plaintiff's view, that the *Zauderer* framework is limited to combating consumer deception 10:02AM in the specific commercial speech at issue regarding the

disclosure requirement, that view of *Zauderer* framework would be in conflict with the DC Circuit's en banc opinion in AMI; correct? Not that that's necessarily fatal. You're in the Fifth Circuit. But just so I understand, your view would create a circuit conflict if adopted by the Fifth Circuit; correct?

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MR. WATSON: It is correct that our position is inconsistent with the DC Circuit's *American Meat* opinion, so I agree in that sense.

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But I don't know if I agree with the word "create," which was in the question, because the Fifth Circuit precedent already demonstrates this, in our view. But it would, I suppose, further the conflict or re-emphasize the conflict.

But we're happy to rely on binding Supreme Court and

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Fifth Circuit precedent for this issue, which we think is clear. And we think that the DC Circuit opinion was, respectfully, wrongly decided.

THE COURT: I would like to wrap up shortly with your argument, since we've been going for about 60 minutes. But

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before I do, would you care to offer any argument this morning on your APA arbitrary and capricious and noticing comment arguments?

MR. WATSON: Yes. I would very much appreciate the opportunity to do so.

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In our view, the rule violates the First Amendment and

the APA.

And as to the APA, the rule is both arbitrary and capricious, and FDA has violated the APA by failing to provide meaningful notice and opportunity to comment.

10:04AM On the arbitrary and capricious point, we flesh out a number of problems in our briefs. But the one that I might focus on mostly this morning is that FDA conducted a flawed cost benefit analysis and incorporated it into the rule, and that renders it arbitrary and capricious.

10:04AM Here, FDA was obligated to -- but did not -- consider whether the rule would reduce smoking under the APA. And in the *Cigar Association* decision from the DC Circuit this year, the court said that, quote: When requiring a product to bear such intrusive and expensive health warnings, it is difficult 10:04AM to image a more important aspect of the problem than whether the warnings will actually affect product usage, unquote. That is an issue that FDA did not consider in this case, and it is one of several reasons why the cost benefit analysis is flawed.

Also, FDA failed to quantify the benefits, which leaves 10:05AM it unable to explain why it chose its approach rather than taking less costly alternatives, such as requiring nine warnings instead of 11.

And the break-even approach that was built into the cost benefit analysis is pure speculation, because FDA provided no 10:05AM reason why the informational benefit is worth more than one

cent per pack.

As I mentioned, there are other reasons why the rule is arbitrary and capricious, but I won't dwell on those for the sake of brevity now.

10:05AM Moving to the notice and comment problem, there are essentially two categories of those problems.

The first is that the government has no justification for failing to release these reports, the qualitative study reports, with the proposed rule, and it also has no

10:05AM justification for subsequently giving the public only 15 days to comment on the qualitative study reports.

Those reports contained hundreds of pages of technical material that was used to inform FDA's quantitative studies. A 15-day comment period didn't provide meaningful notice and

10:06AM opportunity to comment, and cases such as *National Lifeline* from the DC Circuit and *Texas versus EPA* from the Southern District of Texas in 2019 support that point.

The government attempts to draw a distinction, though, between a primary comment period and a so-called supplemental

10:06AM comment period. But even if such a distinction generally exists -- which I don't think it does -- the FDA was required to release the qualitative study reports in the first instance, and its failure to do so doesn't allow it to benefit from a more lenient standard in any so-called supplemental comment

10:06AM period.

The second bucket of our notice and comment argument pertains to the study data, and the government ignores the many cases we've cited for the proposition that FDA was obligated to release the underlying data from the studies to the public during the rule-making process.

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And on the notice and comment point, and the APA points more generally, some of the briefing is focused on the prejudice question, and so I think it is important to highlight that plaintiffs were prejudiced by both notice and comment violations. And under the Fifth Circuit standard, agency mistakes are harmless only where they clearly have no bearing on the procedure used or the substance of the decision reached. That's the *Sierra Club* case at 444.

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And the *City of Arlington* case from the Fifth Circuit also says that courts should consider the likely affect on perceived fairness of the procedural violation that has been found.

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Here, it has a huge affect on our ability to comment and to challenge the rule for a host of reasons, but just to pick a couple very quickly.

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Dr. Iyengar did a study -- which we submitted in the administrative record -- that she had had the reports, the qualitative study reports or the data, it would have allowed her to do things such as including questions about whether using "can cause" rather than "causes" would increase

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believability and decrease confusion. She also could have used the reports in the data to deepen her testing of whether the warnings provoked negative emotions.

Also our medical experts submitted declarations in the 10:08AM administrative record about whether the warnings were misleading, and the qualitative study reports would have helped them to make more robust and move detailed and pervasive declarations if they had had that.

We tried to demonstrate in the our opening brief and 10:08AM reply brief the ways that the reports in the data are relevant. That's why we attached an appendix to each of our briefs that contains certain excerpts from the qualitative study materials. And in our reply brief, at which point we had finally gotten the raw data, we actually quoted the raw qualitative data 14 10:09AM times in our reply brief, which demonstrates just how important it was.

So those are the reasons that we believe that the rule violates the APA for those, and those in our briefs.

THE COURT: Very good.

10:09AM Mr. Watson, let me ask you one final question. This is concerning remedy. Your motion for summary judgment asks for summary judgment that, among other things, enters a permanent injunction against enforcement of the final agency rule under review here. In the DC Circuit's 2012 opinion, in RJ Reynolds 10:09AM versus FDA, the panel majority held that when a district court

determined that the agency acted unlawfully, ordinarily the appropriate course is to remand to the agency. And so the DC Circuit then, as a result, questioned the district court's injunction, and ultimately set aside the agency action and remanded rather than vacated the permanent injunction issued by the district court.

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So my question to you is: Is that a good law, in your view? And even if your legal arguments have merit, would this Court err by entering a permanent injunction under that rationale?

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MR. WATSON: It's a great question; and there are four points I'll try to hit very briefly in response to that, all of which I think are important.

The first is that vacatur -- which is, as you know, what the DC Circuit did, it vacated the rule in its entirety -- that is certainty an appropriate remedy, and it is one of the remedies that we are seeking here. And the Fifth Circuit would agree. The *Chamber of Commerce* case at page 388 from the Fifth Circuit is an example of a situation where the definition of fiduciary was invalid there, and the court vacated the rule. So vacatur is an appropriate remedy, and we are seeking it.

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Secondly, the government's arguments about the alleged inappropriateness of a nationwide injunction here are really focusing on the propriety of extending the injunction to non-parties. That's really the objection that they make. And

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I would note that it's inconsistent for the government to now claim that it would be improper for this Court to grant relief that runs to non-parties, when the government's previously asked the Court for a stay at the effective date the first time around, and that stay extended to non-parties.

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The third point I would make is that the Fifth Circuit has made clear that nationwide injunctions are permissible and may even be required in APA cases. The *Texas versus United States* case from the Fifth Circuit in 2015, at page 188, in footnote 211, discusses why an injunction that extends nationwide, i.e., to non-parties, was appropriate there and was consistent with the extensive judicial power.

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And the fourth point I would make is that a nationwide injunction, when nationwide relief is needed in order to give complete relief to the retailer plaintiffs who sell cigarettes manufactured not only by the plaintiffs here but by at least one manufacturer that is not a plaintiff here, and, thus, to give them full relief, the injunction should extend to all parties, not just the parties to this particular case.

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So those are -- I'm happy to answer any other follow-up questions, but those are my initial responses to your question.

THE COURT: One follow-up question is: What's your best argument against the government's suggestion, I think, in their reply, that even if vacatur and remand were the correct remedy under the APA, that the severability provision of the Tobacco

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Control Act, which is also a Congressional enactment, is more specific and therefore controls and would require only severing certain provisions of either the act or the rule, rather than vacating and remanding altogether?

10:13AM MR. WATSON: That's a very interesting issue, and I think there are three points I'd make in response to that.

The first is that, in our view, the rule is invalid in its totality; and, thus, it needs to be invalidated in its entirety. Most of our arguments, if accepted, would invalidate

10:14AM the entire rule.

For example, the notion that the warnings are unduly burdensome, or that the informational interest is insufficient, or our APA arguments, and there are others. So a number of them would just invalidate the rule entirely.

10:14AM Secondly, even if the images were legally problematic, the textural statements can't be severed from the images because the TCA expressly and specifically provides that the text must, quote, accompany the images. And that is a more specific command that addresses the very particular issue here,

10:14AM the general severability provision that exists in the TCA. So, in other words, it's a specific that governs the general situation. And the TCA commands the graphics that accompany the textual statements is more specific because it speaks to severability in this particular context.

10:14AM The *Miller versus Albright* case from the Supreme Court

has an interesting discussion in a Justice Scalia concurrence about specific governs the general in a severability context, so that is something I would cite the Court to.

THE COURT: That concludes my questions initially for plaintiffs.

For the benefit of court personnel, I'm going to take a brief, say, seven-minute recess, and then we will resume with hearing argument from Mr. Baer for the defendants. So please stay on the line. We will not close out the line. I will simply mute my line, and come back on at 10:22 Central Time.

[PROCEEDINGS IN RECESS]

THE COURT: The Court will now resume the hearing from our recess.

Before we get started, let me again cover a few preliminaries.

Mr. Baer, you mentioned you will be presenting argument for defendants.

So at this juncture let me pause and ask the court reporter and you, to ensure that you can be heard.

Mr. Baer, are you on the line, and would you please make yourself known?

MR. BAER: Thank you, Your Honor. I am on the line. This is Michael Baer from the Department of Justice on behalf of the defendant.

THE COURT: And may I ask that the court reporter

continues to be able to hear Mr. Baer?

[STENOGRAPHIC COURT REPORTER CLARIFICATION]

THE COURT: Very good.

Is everyone ready to proceed with the hearing?

10:23AM Mr. Watson?

MR. WATSON: Yes. I'm ready to proceed. Thank you, Your Honor.

THE COURT: Mr. Baer?

MR. BAER: Yes, Your Honor.

10:23AM THE COURT: Okay.

Mr. Baer, I do intend to let you make your most synthesized version of the argument as well; but before I do, let me preview a question that may require some attention from one of your cocounsel, in case they wish to work on that while

10:24AM you're presenting argument. That question is for defendants to please provide specific citations to the joint appendix for all of defendant's support on the past deceptions point. That is, the support for defendant's assertion of past deceptions by the tobacco industry and when they were and how this rule may be

10:24AM intended to affect them.

I don't anticipate you would have that your fingers, but I would intend you to answer that question at some point in your argument, and wanted to preview it in case one of your cocounsel would care to be doing any work on that while you

10:24AM present argument.

So, with that, let me turn it over to you and ask you to make your opening or summary of argument.

MR. BAER: Thank you very much, Your Honor. Again, this is Michael Baer for the Department of Justice on behalf of the defendants.

10:25AM

Your Honor, if I may, I'd sort of like to step back and set the scene a little bit as to both why the cigarette health warnings at issue here are necessary and how they came about, because they did not just arise overnight. They were the result of decades of congressional and regulatory attention to the lack of public knowledge of the dangers and risks of smoking cigarettes, and they were the product of a particularly extensive, exhaustive effort on the part of the Food and Drug Administration to investigate both the science surrounding the health conditions addressed in the warnings as well as the communication science around how to effectively ensure that members of the public understand the risks of what are, arguably, the most dangerous consumer product widely available.

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So, Your Honor, that sort of congressional and regulatory journey began in 1965, when Congress passed what is known as the Labeling Act, and that was the first time that the surgeon general's warnings were required on cigarette packages. And from the outset, the policy and purpose of that act was to establish a system of warnings through which the public may be adequately informed about any adverse health affects of

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cigarette smoking. So, in other words, from the statutory language early on, from the get-go, ensuring that the public understands adverse health affects of smoking was a key part of this regulatory architecture. And that's continued over the years as Congress has returned to the question of how best to inform members of the public about those risks.

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And so the warnings, the content of the warning gets changed through legislation in 1969. And then, again, in 1984, Congress expands the warnings that are required and establishes the four surgeon general's warning that we have today.

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Then, of course, as relevant here, in 2009, through the passage of the Tobacco Control Act, Congress required larger warnings, with pictorial contents, that are the source of the authority that FDA implemented when it issued the rule that's at issue today. That rule features 11 health warnings that describe and depict some of the lesser known consequences of smoking.

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And, Your Honor, here may be a good point to address one of the questions that Your Honor flagged at the outset. I, candidly, have not received further information yet from my cocounsels. But in anticipation of the question of past deception on the part of the tobacco industry, I did just want to note that at least one piece of evidence that we cite is, of course, findings from past court causes on this issue, and I invite the Court to consider the *United States versus Philip*

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Morris court decision at 449 F.Supp.2d 1, and so the citation is going to be from page 855. And, there, in terms of characterizing efforts of deception, the Court there noted that, quote: Those efforts were, quote, demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted efforts to attack and undermine the studies of mainstream scientific publications, such as the Reports of the Surgeon General.

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In other words, for decades, the tobacco industry had launched a concerted campaign to call into question the linkage between the health affects, the negative health consequences of smoking, and the consumption, obviously, of cigarettes.

I was, frankly, a little bit startled to hear some of the same echoes of those messages come through in Mr. Watson's presentation, questioning the accuracy of the causal statements just in the text warnings that are at issue here, and again, calling into question more broadly a track record of deception. But, Your Honor, for purposes of today's case and today's hearing, I don't think the Court needs to wade into the waters of the industry's history of deception to hold that these warnings are fairly constitutional.

And so turning to the First Amendment analysis here, as we note in our briefs, the appropriate standard to apply to assess the constitutionality of these pictorial health warnings

are the standards set out in the Supreme Court's *Zauderer* case.

Now, the reason that *Zauderer* applies -- plaintiff's phrased it as a threshold requirement, and, frankly, I don't think it matters much for purposes of this discussion whether it's a threshold requirement or just a requirement that is a part of the *Zauderer* inquiry -- but the threshold requirement there is that the disclosures at issue be purely factual and uncontroversial information.

10:30AM But before we even get to that requirement, plaintiffs, of course, have suggested that the whole concept of the *Zauderer* case law is inapplicable here, given the nature of the government's interest, and so I'd like to start there. Because as I understood plaintiff's argument and as I read their briefs, they have not disputed that every single court of 10:30AM appeals that has considered the issue has come down unanimously in favor of the proposition that the interest described in *Zauderer* -- sorry -- the interest that regulations evaluated under *Zauderer* are designed to address are not limited to preventing consumer information, consumer misinformation, or 10:30AM consumer deception, and it's certainly not so limited as to remedying consumer deception in the same advertisement or form of commercial speech to which the disclosure requirement is appended.

THE COURT: Now, Mr. Baer, you mentioned the circuit 10:31AM courts. Has the US Supreme Court ever applied *Zauderer* to

compel disclosure requirements that were not designed to correct misleading commercial speech?

MR. BAER: So, Your Honor, I don't believe the Court has ever, at least, expressly stated that it has applied *Zauderer* to uphold a commercial speech disclosure requirement in those circumstances. But I would note that in *NIFLA*, for example, the Court was very clear in distinguishing the facts of that case, which, at least with respect to the one of two notices at issue there, it said *Zauderer* was not the appropriate lens in which to view it. The court was clear that it was not questioning longstanding health and safety warnings; and, for one of the mill commercial disclosures, long considered to be legal. And so, there, I think the court was drawing a contrast between the type of disclosure requirement that was at issue for licensed clinics in *NIFLA* with other types of disclosures of sort of purely uncontroversial factual commercial information that occur sort of throughout society, and I don't think that distinction or that contrast makes sense unless the court was recognizing that *Zauderer* would apply in accepting the legality of those longstanding long-required disclosure requirements.

THE COURT: What do I do with the purely factual and uncontroversial requirement, given that plaintiffs, at least, maintain that even some of the textual warnings themselves are controversial by suggesting causation significance that does

not exist?

MR. BAER: I'm sorry, Your Honor, I'm quite sure I caught the question there.

THE COURT: Let me rephrase it then. In your
10:33AM opposition, I believe this is at PDF page 33, you state that the plaintiffs do not disagree that the textual warnings required by the agency rule are uncontroversial. I posed that question to plaintiffs a moment ago, and they quite vigorously argued that some of the warnings were factually controversial.
10:33AM Could you justify your assertion that there's dispute on the controversiality of those statements?

MR. BAER: So, certainly, if plaintiffs are disputing it, then they are, of course, creating the dispute.

In terms of justifying the statement at the time we made
10:34AM it in our opening brief, that was certainly our best reading of their initial summary judgment filing here. Which, as we read it, focused the criticism of the factual controversial nature of the warnings on the images and the suggestion that those images created to -- led to exaggerated impression of the
10:34AM negative health consequences of smoking.

I would say, though, it wasn't entirely clear from Mr. Watson's argument, but I still don't take the plaintiffs to be questioning the factualness of the statement at issue in the warnings. In order words, although they may suggest that there
10:34AM are misleading impressions that could come from those

statements -- and we can turn in a moment to why I think that argument isn't well supported -- I hope that they are not questioning that cigarette smoking causes all of the health conditions identified in the warnings because that -- such a sort of contention would run afoul of the scientific consensus that is reflected in the 2014 surgeon general's report.

But I'm not aware of, more broadly, scientific evidence that calls into question the accuracy of those statements. So I sort of hope that that, at least, can be kind of beyond the realm of questioning for purposes of this argument.

THE COURT: Do you disagree, and why, with then-Judge Kavanaugh's statement and concurrence in the *AMI* case that governmental interest in promoting awareness is insufficient, legally, to establish a substantial interest because it's essentially circular and so vague that it would undermine that requirement altogether?

MR. BAER: Your Honor, I don't think Judge Kavanaugh -- or then-Judge Kavanaugh's, excuse me -- concurrence in *AMI* to be stating quite so categorical a proposition. Rather, I think it's consistent with the holding of the Second Circuit in the *International Dairy Foods Association* case, which is to say that of course the government can't justify the disclosure requirement for the sake of consumer curiosity or information for information sake, divorced from any significance or importance attached to that information. And one of the pieces

of then-Judge Cavanaugh's reasoning that is consistent with that fact is sort of pointing to historical precedence as a basis for findings that there is legitimacy to an interest -- so pointing to decades of congressional actions or findings on
10:36AM a particular issue -- is a way of being able to sort of separate the wheat from the chaff and to say, okay, yes, the government does have an interest in ensuring that this kind of knowledge or information is out there, versus this is just sort of feeding the consumer curiosity. So, here, I would contrast
10:37AM the record of, again, decades of congressional attention to the importance of individuals having information about the negative health consequences of smoking with the information that was at issue in the Second Circuit case where there was a disclosure requirement about whether cows were treated with hormones,
10:37AM where the court went out of its way to emphasize that there wasn't any suggestion that that information was somehow salient or important for matters of public health.

And so absent that connection to a consumer could use this information in a way that would actually affect that
10:37AM consumer's health or wellbeing, you know, there isn't a sufficient justification for the disclosure requirement.

THE COURT: I'm sorry to interrupt you.

Just to articulate that in my own words, your limiting principle is that an interest in promoting consumer awareness
10:38AM is sufficient if that interest stems from or is related to

public health or sort of a common sense prediction that consumers would want to know this information before deciding whether to purchase or use a product?

MR. BAER: So I think those would certainly be a way of phrasing it or framing it. I don't even know that you need to get to the point of sort of predicting what consumers want if there was something -- because, again, I think the consumer-want test both gets a little bit in the consumer curiosity problem but also potentially ignores in which the government makes a considered judgment that there is a certain -- there's certain information that whether it's for the sake of public health or for the sake of the functioning of democracy, as in the *Citizens United* example that we cited and that plaintiffs actually cite in their own brief. There are certain categories of information that I think is reasonable for the government to attach salient or significant to, and to say that we think it's important that an informed public have access to that information to make important choices.

THE COURT: Sort of, what percentage of the public would want to know information before there can be a substantial interest in compelling manufactures to disclose that information? Do you have any thoughts on that in the abstract or with specific examples?

MR. BAER: So again, Your Honor, sort of consistent with my last answer, I think I would at least somewhat push back on

the notion that we should think of it in terms of what percentage of the public wants to know the information. And I think the evidence for pushing back on that suggestion comes from sort of the foundational Supreme Court cases that we cite that deal with informational interests. You know, in the *Citizens United* case, I don't take the court to be interrogating when, in a holding, the disclaimer and the disclosure requirements that were at issue there -- I don't take the Court to be interrogating how much of the public would want to know information about, for instance, the financing of certain election related communications. Rather, the court was making a sort of more objective principled characterization or argument that it's important for the public in a democracy to have information about who is financing that type of speech because that allows the public to participate more effectively in the democracy and to be more informed and to make informed choices,, and so I think there is room for the government to make those sorts of value-based judgments.

I do think, here, just to return to an earlier framing that Your Honor let out, there is sort of just common sense indicates that whether you're going under the knife for surgery or whether you're making a run-of-the-mill purchase at a convenience store, it's important to be able to know that something may give you bladder cancer, something may cause blindness, that something may cause harm to your children.

These are all kind of basic pieces of information about, in this case, a product millions of Americans put into their body, that I think common sense dictates the government has substantial interest in ensuring that individuals are aware of.

10:41AM THE COURT: Right. And the *Zauderer* test requires courts to decide if there is a substantial interest. Even *Central Hudson* looks at the substantiality of the interest. And so I'm a struggling with trying to understand how that applies. Courts have recognized that that's something of an

10:42AM open-ended test. If it is a test, it has to screen out some things, one would assume.

So can you give me an example of an interest that would be screened out by that test, if not a substantial government interest?

10:42AM MR. BAER: Absolutely, Your Honor. And apologies for returning to a case we've already discussed. I think the consumer curiosity example is probably the clearest one here. That, even if there is public demand for a certain kind of information -- and I think, in the context of the Second

10:42AM Circuit *International Dairy Foods Association* case, there was interest in knowing whether cows were treated with growth hormones. That consumer interest alone isn't sufficient because it's not linked to any sort of decision of significance for individuals. There wasn't a way in which it affected --

10:43AM had the potential to affect their health or wellbeing in a

meaningful way.

THE COURT: What about information that, if consumers learned it later, it might cause them stress? One of the warnings here is about stunting fetal growth. Another thing that I believe is shown to stunt fetal growth is stress, stress to the mother. So can the government require disclosure of information that if learned might create stress, so that mothers can avoid buying products that might later cause that stress?

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MR. BAER: So, Your Honor, just as kind of an initial housekeeping point, I think sort of, analytically, we may be getting out of the realm of what interests are -- can constitute substantial interest and getting into the realm of then once there is an interest the disclosure at issue, you know, is reasonably related or not, unjustified and unduly burdensome to that interest.

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And I say that only because I think, to Your Honor's question, of course the government has a substantial interest in informing women about the risks to their babies that may come from consuming a particular product, that sort of a foundational informational interest. And then, if there were to be an argument that the benefits of giving that information aren't worth it in a particular case, I think that would get to the sort of more substantive application of the other part of the *Zauderer* inquiry. And I'm happy to talk about why I think

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that would easily be satisfied here. Although, I don't understand plaintiffs to have sort of made that trade-off argument in this case.

THE COURT: So you think it could be constitutional under the First Amendment for the government to compel manufactures of other products to occupy half of their front label with the same picture that is in the agency rule here and with the warning that this product may cause stress that stunts fetal growth?

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MR. BAER: So I think, in the context of other products --

THE COURT: It could be social media usage invites stress that may cause fetal growth, so now some social media platform has to display this graphic. Would that qualify as a substantial interest?

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MR. BAER: So, again, I do want to sort of separate the question of the substantiality of the interest from then the application of the rest of the *Zauderer* inquiry. So a substantial interest in informing individuals about the risks to their health or to the health of their fetus from certain products or services, without knowing kind of the specifics, it's a little hard to weigh in. But I think, at least in the abstract, of course, there could well be a governmental substantial interest in providing that fundamental health and safety information.

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But to the question of whether or not -- to the other part of Your Honor's question, that means the government can sort of automatically require large warnings that take up 50 percent of a product's packaging, I think there are a number of steps that you would have to clear before you would even ask or that question would even be presented, and then perhaps even more before the question would be resolved in favor of the government.

10:46AM

And, in particular, I think what separates cigarettes from a number of other products where we might imagine that there are health risks are, first, again, the decades of congressional attention to the problem. Related to that, the efforts that Congress has made to tweak and refine its warning system over time. The findings that those tweaks and efforts haven't been sufficiently effective. And then, finally, a year's long record full of robust research about the degree to which both there is not sufficient information about the health risks that these warnings address and also evidence of the extent to which these warnings promote understanding of those specific health risks. And I recognize all of that is a bit of a mouthful, Your Honor. But the point of emphasizing all of those steps in the process is you only get to the kinds of warnings you have here after those kinds of steps or steps of those sorts of magnitude.

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And I think, then, it shouldn't be surprising that the

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only warnings that we've seen of this nature are for the most dangerous widely available consumer products in the country.

THE COURT: So, here, you would screen out some of those hypotheticals not so much at the substantial interest stage but at the unduly burdensome stage, based on the anticipated facts of those hypotheticals?

MR. BAER: Exactly, Your Honor.

As I read *Zauderer*, the sort of unjustified and unduly burdensome part of the inquiry, the sort of the flip side of the reasonably related part of the inquiry, and it's at those stages that you would screen out some of those hypotheticals. Because I think there would need to be a record akin to what we have here, and I mean that both in the terms of the scientific administrative record but also in terms of, again, kind of the congressional regulatory record that bolters the appropriateness of requiring these kinds of disclosures on these specific products.

THE COURT: Would the burdensomeness test screen out graphic warnings if the stakes were not to help a consumer but also the quite severe stakes of whether a product was made with slave labor in other countries?

This is just by way of a hypothetical to help limit your argument. But what about a hypothetical mandate for certain products, whether it be a chocolate bar or a piece of technology, to bear on their label some graphic warning that in

the government's view they were made with slave labor or some other sort of abhorrent legal practices in other countries?

MR. BAER: A couple of thoughts and reactions to that, Your Honor.

10:50AM First, although we've been talking about sort of the substantiality of the interest in sort of a purely informational sense, that, of course, doesn't preclude the government from asserting an interest under *Zauderer* in ultimately affecting consumer behavior.

10:50AM And so, for instance, in then-Judge Cavanaugh's analysis in AMI, he ultimately agreed with the results there because of the finding about the disclosures of the country of origin of meat products would promote consumer behavior to buy American meat. And I say all of that, just by way of Your Honor's

10:50AM hypothetical, one could imagine a spectacular analysis applying to products made with slave labor, you know, that the government has an interest in affecting consumer decisions about that.

Although, the caveat I would give in that instance is,

10:51AM depending on how such a disclosure requirement were characterized, you might run into the kind of a problem that you had in the *Entertainment Association* case out of the Seventh Circuit or the *National Association of Manufacturers* case from the DC Circuit, where, in the Seventh Circuit case,

10:51AM you had a warning label with the number 18 on it, and that was

to be appended to sexually explicit material, and where in the *National Association of Manufactures* case from DC you had the conflict-free certification that needed to be disclosed, and in both cases the court found that those were essentially sort of value judgments, subjective judgments, that didn't qualify as purely factual and uncontroversial.

And I just note all of that by way of saying you would, of course, have to interrogate whether products made with the slave labor determination was factual and uncontroversial, as opposed to something that was the subject of significant and bona fide disputes.

THE COURT: What is your response to the plaintiff's argument, which echoes the panel majority in the 2012 RJ Reynold's decision, that the graphics are sufficiently open-ended, that they require interpretation by the viewer, and that that open-endedness and that need for interpretation renders them sufficiently either non-factual or at least sufficiently controversial that it does not meet that *Zauderer* framework element?

MR. BAER: So I disagree with that, the plaintiff's characterization, Your Honor. And I disagree with it for several reasons.

The first is that, as we note in our brief, that sort of seems to be an argument against using all images, whatsoever, in warnings. And so, for instance, you could imagine even just

an abstract image, a symbol, like an exclamation point in a triangle -- which we often understand to mean warning, but individuals could have varied reactions or responses to -- but that somehow wouldn't prompt to purely factual and uncontroversial information.

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Similarly, we note any existing cigarette warnings --

THE COURT: But no one thinks an exclamation point in a triangle is a grammar teacher instructing people on proper punctuation. Whereas, at least, arguably, here, some of the pictures do require interpretation.

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What do you make of a person, with their chest exposed and stitches going down it -- there's degrees of causation that may be controversial; correct?

MR. BAER: So, Your Honor, I maybe want to separate out that last part of your question from what I understood to be the preceding piece, which I understood the preceding piece to be getting at the question of how much sort of interpretive leeway is there for which kinds of images, and aren't the images here sort of more prone to multiple interpretations. And I'd say a couple of things on that first point.

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Which is, first, that right now we're talking about these images, but as a general rule I don't think it makes sense to think about the images as divorced from the text. That, of course, these warnings are appearing as text image pairs. And so even if in the abstract an image might be

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subject to different or multiple interpretations, I think when paired with clear textual warnings, as they are here, there's much less concern about the sort of image clarity. And I think when compared --

10:55AM THE COURT: Regarding that point, what role does the language counterpoint have? One argument is there's a substantial portion of this country -- not a majority -- but a substantial portion that has limited English proficiency. Does that undermine the argument that image and text have to be 10:55AM considered as a pair if the text cannot itself be comprehended by some substantial part of the country?

MR. BAER: So, respectively, Your Honor, I don't think it does. Because I would just note that for that category of individuals, if you have only a text only warning, then they're 10:55AM getting absolutely no information and could view a text only warning as almost, literally, an infinite number of possibilities. The image at least sort of narrows the focus and the realm of possibilities, and it particularly does so in the context of being appended to the cigarette advertisements 10:56AM or warnings.

In other words, to use Your Honor's example from a few moments ago of the warnings image that accompanies the textual warning about heart disease and strokes that can be caused by blocking arteries -- which cigarette smoking causes -- putting 10:56AM an image of a man with the sort of surgery marks on his chest

that appears in that image on a cigarette package, I think, naturally leads to the linkage between cigarette smoking and that consequence. And even if one doesn't purposely understand sort of all of the detail in the text because one doesn't speak
10:56AM English -- although, I would, just as a brief aside, Your Honor, note that there are also Spanish language versions of these warnings that FDA prepared and at are issue here -- that that information, again, it's still accurate and within a much narrower realm of bounds of what a viewer of that warning might
10:57AM think it's about than a text warning that are they're wholly incapable of reading.

THE COURT: Let me also circle back little bit to the abstractness of the governmental interest asserted here. Is the FDA, are the defendants, in any way distancing themselves
10:57AM from an asserted governmental justifying interest of either reducing or at least maintaining from increase of prevalence of smoking?

MR. BAER: The government is not defending this rule on that basis. Which, just to be clear, is a separate statement
10:57AM from whether the government as a whole or FDA as a whole is distancing itself from that interest in other rule makings or other agency actions, because I think that the agency's record speaks for itself there.

THE COURT: So help me understand, why are the
10:58AM defendants adopting that limit? The asserted governmental

interest in this rule of promoting consumer awareness is not just so the consumers can sort of appreciate the beauty of knowledge; right? It's so the consumers can act on that knowledge; correct?

10:58AM MR. BAER: Yes. So that consumers have information to be able to make more informed choices; and, obviously, one of those choices may well be to stop smoking. But the government -- or to not take up smoking to begin with. But the government is not justifying these warnings on the basis of a 10:58AM sort of an empirical prediction of how that will play out.

Your Honor, I thought the colloquy you had with Mr. Watson earlier about the consumer deception cases and interest was sort of on point to this line of inquiry, where in other contexts where we think about information being important 10:59AM to consumer choice there isn't then a subsequent interrogation of whether having corrected for deception or having prevented deception, consumers, in fact, make different choices. There's no part of *Zauderer* that deals with, well, how many customers are going to be dissuaded from retaining the services of the 10:59AM attorney who is advertising contingency fee based representation, or, in *Milavetz*, no finding about how many fewer customers' debt release that people have that they have to disclose that the prospect of using their services could include filing for bankruptcy. There's just -- I think that's 10:59AM sort of acknowledged then in the case law and again here in

sort of the legislative history, specific to cigarette health warnings, that this is information that's important to consumer choice.

And the most recent iteration of that, of course, comes from the Tobacco Control Act itself, which as Your Honor mentioned earlier with Mr. Watson, in Section 202(b) of the Tobacco Control Act, Congress singled out the interest in promoting greater public understanding of the risks of cigarette smoking as an interest that is sort of the touchstone for making any changes to the warnings here.

THE COURT: Right. I think it's hard to deny that that's the interest, because it's asserted in the statute, is promoting greater public understanding of the risk associated with the use of tobacco products, at Section 202(b); or, Section 201(a), depicting the negative health consequences of smoking.

I guess my question, though, is why does the government resist -- what seems to be a common-sense proposition -- that the reason for promoting that greater public understanding is to reduce or at least maintain without increase a rate of smoking? If you're trying to educate people about the downside of something, when, in theory, the reason you're doing that is, again, not just the beauty of knowledge, this is not promoting awareness of other religions so we can appreciate them and live in harmony more, it's because the government wants to decrease

or at least not increase the prevalence of smoking; correct?

MR. BAER: So, again, Your Honor, I don't deny that in other regulatory actions the FDA has undertaken there is this focus in having that affect. And it certainly is a plausible characterization of what may happen in the future, that fewer individuals will smoke once they're better informed of the negative health consequences of smoking.

But to the specific question of whether that is the reason why there is value in the informational interest, I actually don't think that's right. I think that, here, the government -- here, FDA -- would think it important to provide this information even if it did not change the number of individuals who smoked, much in the same way that the government might require fully informed consent and therefore disclosure of certain health risks for surgery.

THE COURT: Two points. First of all, I'm not suggesting that it would have to change the number of people who smoke. This information, the government could want to get it out there just so that the number of people who smoke doesn't increase, and that would still be smoking prevention in the sense of preventing it from increasing from where it would be without the warnings; correct?

MR. BAER: Yes. As I understand the question, yes.

THE COURT: Secondly, I understand your legal point about this doesn't have to be the touchstone for assessing

either the First Amendment fit or the arbitrary and capriciousness under the APA, but I guess I still don't understand how -- are you denying -- the title of the act is the Family Smoking Prevention and Tobacco Control Act. Doesn't the title of the act itself say that one of Congress's purposes in mandating these warnings was to prevent smoking? Isn't it called the Family Smoking Prevention and Tobacco Control Act? Isn't that the title of the act?

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MR. BAER: That is, of course, the title of the act, Your Honor. And there's no doubt that, in thinking of the statute as a whole, that was indeed of one of Congress's purposes.

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THE COURT: Okay. Again, I understand you are making new arguments about that doesn't have to be the touchstone for assessing the validity, the free speech validity or the APA validity. You're not denying that the reason that Congress wanted these warnings was to prevent smoking; right?

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MR. BAER: So, Your Honor, on that particular point, I actually don't know that we can say that that was the reason that Congress wanted these particular warnings, especially when you consider that the language Congress used in Section 202(b) goes to promoting greater public understanding.

11:04AM

Now, Congress -- I don't deny that Congress may have thought or hoped that one consequence of promoting greater understanding would be to either hold constant or decrease

smoking rates, but I don't know that we sort of know specific to this provision what Congress is thinking on that point.

And just to sort of emphasize or to sort of drive that point home a little bit, Mr. Watson earlier was talking about the DC's Circuit recent decision in the *Cigar Association* case where, there, the DC Circuit was considering a separate provision of the Tobacco Control Act that did require for certain regulatory undertakings -- and, to be clear, those regulatory undertakings are different from the warning requirements that are at issue here -- but for this other category of regularity undertakings under the TCA, Congress did include a requirement that there be a finding as to the affect of the regulation on smoking rates. So Congress was attuned to that issue and chose to require that sort of consideration or finding in some aspect of the TCA but not others, and it didn't choose to require that kind of finding or undertaking here.

THE COURT: And then, related to the graphical part of the warnings here, defendants are also not seriously denying, right, that the graphics were selected, in part, because they are stark and captivating; correct?

MR. BAER: I don't deny that they were selected, in part, to ensure noticeability. I think stark and captivating gets a little closer to some of the considerations that the government I think very consciously was striving to avoid in crafting these images. But, certainly, the record is clear

that a key aspect of the understanding is noticing the warning and attending to it, and so these warnings were, indeed, designed to further that interest.

THE COURT: There's no particular magic to those words I selected. But the whole idea, right, was that having the graphic images -- which some describe as grotesque -- were designed to captivate consumer attention or potential consumer attention, and make the information on the FDA's argument more readily communicated and it would take; right? That was the whole idea, was it would increase the informational value?

MR. BAER: Yes. That it would increase the informational value by getting consumers to notice and attend to the warnings. And as Your Honor, I think, put it well, ensure that it improved the communicative function or ability for individuals to sort of digest and retain that information.

THE COURT: And so one of the questions I have to ask, under the *Zauderer* framework the government's arguing should apply, is whether the compelled disclosure is unduly burdensome. And there will always be -- at least, up to certain limits, there will always be an argument that even larger and bolder and more captivating graphics would better capture consumer attention and better communicate a message. So what is the line at which the increased effective communication rationale runs out and compelled disclosure does become too effective? Is it 75 percent of the packaging of

cigarettes? Would that be unduly burdensome?

MR. BAER: So, Your Honor, I think picking a percentage as to where that line exits is, I think, sort of a difficult undertaking, and, frankly, one that I think may not be necessary here, given what the record found in terms of warnings of the size -- or given what FDA found based on the record in terms of how warnings size correlate to effectiveness.

11:08AM

And, here, the FDA made express findings -- that I don't understand to have been controverted by plaintiffs at any point in their briefing -- and this is at pages 15,650 to 51 of the final rule, which is at 85 Fed Reg, quote: The scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to and read the messages conveyed by the warnings.

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So I think something within the ballpark of what you have under the rule is necessary. And if you were to get much larger than that, you might well get into the realm of unjustified or unduly burdensome, because it would no longer be reasonably related to the government's interest, it might no longer be supported by the record, by the literature, and you could have, of course, also insufficient time or insufficient space for the communication of the manufacturer's message.

11:09AM

THE COURT: I may come back to that, the *Zauderer*

11:10AM

framework, in a bit. But I do want to be sure to ask about *Warner-Lambert*.

In the 2012 DC Circuit opinion, there the court there noted that although the amicus states had suggested relying on *Warner-Lambert* and limiting past section, that the FDA there did not frame that rule as a remedial measure for past deception claims. Some of the amicus support here notes *Warner-Lambert*. Did you clarify the extent to which the defendants are relying on *Warner-Lambert* in remedying past deception in defending the agency action shown here?

MR. BAER: So, yes, Your Honor. We're relying on remedying a past deception theory fully in the alternative because we don't think it's necessary to reach that issue under *Zauderer*.

And, here, the argument is that the lack of consumer information about these negative health consequences stem from a decade's long effort to try to either convince the public that cigarettes are not dangerous or to muddy the waters. I believe during Mr. Watson's argument he suggested that there was not evidence pointed to in our reply brief -- or sorry -- in our briefing regarding sort of this history. And I would just note that, in our reply brief, at page 5-2, we did cite, for instance, administrative record 39,667, which describes how tobacco advertising used, quote, key words such as smooth, mild, to convey health related messages, and that it later

relied on imagery of active, healthy models for what was characterized as a, quote, more subtle message about health. Which is, again, just more evidence that the tobacco history has a history of using its speech to suggest that cigarettes
11:12AM are not connected to health risks and are consistent with a healthy lifestyle, and it's from sort of that kind of foundation of misinformation that the public may be under-informed about any number of particular health risks associated with smoking.

11:12AM THE COURT: Let me try to present my understanding of plaintiff's slippery slope argument, and then the ultimate question is what assurances can you offer that you understand it and that it is not as slippery as the plaintiffs say it is.

The plaintiff's argument is, essentially, that if the
11:13AM interest required by either *Zauderer* or *Central Hudson* is something like reducing smoking, and a certain set of warnings has not been shown to sufficiently further that interest to justify compelling those warnings, that if the government can then redefine the interest as simply promoting education, which
11:13AM is one of the means of reducing smoking, and then say that the same warnings are effective to promote education, that the interest requirement, substantial interest requirement, is effectively undermined.

I think your response is something to the effect of
11:13AM sometimes the government can have different levels of interest,

and public health might be the broadest conception, and reducing smoking would then be a subset of that or a means to improve public health, and promoting education is also a means of reducing smoking. And that you would, I assume, argue that
11:14AM sort of the means end test doesn't really have any conceptual support or significance, since you can always abstract up or down, higher, to a more abstracting or less abstracting interest. But, nonetheless, that argument troubled the DC Circuit in the 2012 decision. It seemed to have troubled
11:14AM then-Judge Kavanaugh in his "may" occurrence.

So do you understand the concern, and what's your best response about limiting the concern?

MR. BAER: So, candidly, Your Honor, I somewhat understand plaintiff's concerns. But I think the principal
11:14AM response is that if the government is choosing to justify warnings purely on the basis of the information that it conveyed in informational interests, then it's sort of have to put up or shut up on the significance of that information and the degree to which the warnings actually achieve it, as
11:15AM distinct from, to go back to the then-Judge Kavanaugh's concurrence in AMI, situations where you could imagine the government having to make some sort of showing or estimate as to effect on behavior in order for that interest to be sufficient. Because absent some test on behavior, it's not
11:15AM clear; it's hard to see why that information has significance.

So contrasting, again, kind of the consumer curiosity versus the sort of fundamental public health or democracy-preserving aspect of the information that we've been discussing earlier.

I guess the other point that I would note is that changing the focus of the interest, it's not just a matter of abstracting up or down; it leads to different substantive results. So in the DC Circuit's decision in RJ Reynolds I, it pointed to the specific aspect of the warnings at issue there that it found concerning and indicative of advocacy consistent with an effort to try to dissuade people from smoking. So things like appending the phone number 1-800-quitnow to each one of the warnings, or one warning had an image of a man with an "I quit" T-shirt on it, the court took those inclusions very seriously and found that that was part of the sort of antismoking brow-beat consumers into quitting advocacy that it found ultimately doomed the rule there.

Of course, here, you have a process that was geared exclusively around promoting greater public understanding of the negative health consequences of smoking, and so the warning text images are focused on ensuring that the images are concordant with the textual warning in a way that promotes consumers' ability to understand the negative health consequence at issue.

So to sort of return to the question of descending down the slippery slope, I don't think it's all sort of one

continuum or one straight line from behavior to information, because I think if the government is focused on different aspects of the problem the results can be different within different implications for a manufacturer or other economic entities' speech, as I think there are here, in ways that are meaningfully different from the implications that were at issue in the first RJR case.

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THE COURT: Part of the justification for this rule and the warnings on this rule is promoting consumer awareness of some of these specific consequences that the FDA found did not have as high of awareness absent these warnings, like COPD, diabetes. If that's part of the justification, then what is your argument that this was a sufficiently narrowed way of doing that, when public information campaigns by the government focused on those specific health consequences could be tried or enhanced without the burden on the expression of manufacturers?

MR. BAER: So, several arguments there, Your Honor.

The first is the threshold. That the framing of that question in the way plaintiff had talked about this issue in their briefing and in argument today sort of suggests an obligation to kind of consider, you know, the various alternatives to some extensive degree. *Zauderer* itself, I think, forecloses that by noting when you're within the realm of *Zauderer* applying you don't have to consider every possible alternative in the way you might of a First Amendment context.

In particular, the language I'd like to focus on comes from *NIFLA*. Because in Mr. Watson's argument, he talked about public advertising campaigns there as being a reason that the court struck down one of the disclosure requirements at issue in *NIFLA*. But as we noted in our reply brief -- and as I don't take Mr. Watson to have responded to in his argument this morning -- there were two disclosures at issue in *NIFLA*, a disclosure for licensed clinics and a disclosure for unlicensed clinics. The disclosure for licensed clinics concerned services that the state of California provided elsewhere, so it concerned not the disclosures at the particular licensed clinic. And so the court found that *Zauderer* as a threshold matter did not apply to the disclosure for licensed clinics because the required disclosure didn't concern that clinic's own products or services, and that, as a result, a higher level of scrutiny would apply.

In applying that higher level of scrutiny, the court then observed that there wasn't evidence about the efficacy of public information campaigns, and that ultimately doomed the disclosure requirement for the licensed clinics. But, again, it did so not under *Zauderer* but under a more heightened form of scrutiny. The court -- by that point in the analysis, *NIFLA* had already ruled out the prospect of applying *Zauderer*. So I don't think that kind of in-depth comparison of public health campaigns on the one hand to the warnings we have here on the

other is required under the case law, and I don't know that the plaintiffs have cited any cases to the contrary.

So even if that level of comparison were required, I think FDA has met its burden; because as is explained in the rule, even if public health campaigns can be affective for certain purposes, they are not -- they don't achieve the sort of decades-long recognized congressional interest in ensuring that every package of cigarettes contain a warning, which ensures that every individual who smokes or potentially smokes who picks up a package of cigarettes is going to be informed about the negative health consequences of doing so. In order words, there's sort of a one-to-one correlation between individuals who are picking up packages of cigarettes and individuals who are exposed to that information, in contrast to a public health campaign which can't reach as broadly or as universally. And so I think that --

THE COURT: I appreciate, the government would love to co-opt every product's marketing at the billboard because it's more affective.

Let me move to a separate question. Just as a hypothetical, but assume that it was beyond big. That no matter how informed the public was about all of the specific health consequences of viewing a product, that some percentage of the public was just always going to make the decision to use the product, for whatever benefits they perceived, personal,

social, whatnot, such that any increased warnings, which might promote more awareness of specific consequences, but given a product's addictive nature or just the nature of a personal decision making it wouldn't actually change any decisions on the grounds to use, and therefore to curb the health consequences of the product. Is the government arguing that there would be a substantial government interest in -- again, this is a hypothetical -- hypothetically, completely useless increased awareness of health consequences?

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MR. BAER: So, Your Honor, I would say that the government would defend the government's interest in requiring those disclosures, but I especially take issue with the word useless there.

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THE COURT: This is a hypothetical. I appreciate that you're raising arguments that there are uses here to consumer awareness, so let me be more precise.

11:23AM

Is there a substantial government interest in increasing consumer awareness of consequences of using a product when it is hypothetically established beyond any doubt that that awareness will not change any decisions to actually use the product and, therefore, incur the negative health consequences that the education is about?

11:24AM

MR. BAER: Yes, Your Honor. A disclosure would be justified there, and I'll explain why.

As Your Honor noted, that sort of hypothetical is

consistent with, for instance, a perfectly addictive product; right? One where, once you have a tried it once, it's impossible to ever cease using it. So if we imagine that kind of hypothetical product being the one we're talking about, then
11:24AM I absolutely do think that there is a substantial governmental interest in ensuring that individuals who are forever addicted to a product that is causing heart disease, causing bladder cancer, causing cataracts, deserves to know the consequences of that addiction. Now, that may be a sort of a tragic knowledge,
11:24AM tragic reality. And you could imagine individuals using that information in any number of ways in terms of how they think about the course of their life and what to expect and what to mentally prepare for, and I could imagine any number of ways in which that is still essential information for consumers.

11:25AM THE COURT: Wait. So you're arguing that even if the increased awareness doesn't actually change the health consequences, there's a use in allowing the people to, like, you know, create wills and get funeral insurance?

MR. BAER: I'm sort of talking more broadly than that,
11:25AM Your Honor. Just that, yes, if you are addicted to a product, you deserve to know what it's going to do to you, and that could be for any number of reasons. Maybe it's long-term planning. Maybe it's just in terms of your own mental preparation for what to expect in your life about the pain that
11:25AM you may suffer or the surgical procedures that you're going to

go through. Maybe it's so that you get earlier screening for particular cancers or particular diseases. Again, you know, separate and apart from purchasing decisions, information about what is going to happen to your body because of a product that you consume, I think, absolutely, that's valuable information and one that the government has an interest in ensuring that individuals are presented with.

11:26AM

THE COURT: I think I understand. You're just kind of moving a little bit away from my hypothetical and drawing it back to this case -- which is fair, since this is the case at hand -- in arguing that it would help users mitigate the health consequences or prepare for them. Right?

11:26AM

MR. BAER: So, yes. Although, to be fair, Your Honor, I wasn't trying to place a hypothetical, at least in this particular line of questioning. Because as I understood the hypothetical, the key premise is that it doesn't affect purchasing decisions of the product to which the warning is appended. Again, my point is, as you could imagine, there's any number of other ways in which it still affects the consumer's life choices and mental processes.

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THE COURT: So, here, the government is not making the argument that even one fewer smoker is enough, even one life saved is enough, or one fewer user is enough, which one could perhaps understand the appeal of that, but that's not the argument the government's drawing on to justify these warnings.

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Instead, it's we don't have to demonstrate that there will be even one fewer user. It's, even for those who use it, there is a substantial government interest in better appreciating more widespread appreciation of the consequences, and that that's justified by those other ends that you mentioned: Preparation, mitigation, et cetera. Is that accurate?

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MR. BAER: I think, broadly, yes, Your Honor. Although I I would add that, in transitioning from the hypothetical back to this case, it is also important to keep in mind the individuals who don't yet smoke.

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And now, going back into the hypothetical realm, even for them, even if you were to assume that their decision isn't affected by the information that's being provided here, sort of going in eyes open to the choice, kind of again like, you know, someone's going to go under the knife for surgery, even if it's inevitable that they are going to choose surgery, knowing the risks, the government has a substantial interest in ensuring that they do know those risks before they make a potentially consequential decision.

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THE COURT: Yes. But, again, presumably, that's because the whole idea of informed consent is that it would, in theory, if the information was about harms, it would allow people to make a different choice.

And I just want to be clear. You're not defending these rules on the idea that without the warnings you can demonstrate

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that some number of people would make a different choice, either not to start smoking or not to continue smoking. You're not making that argument. You're just arguing that there's still substantial government interest even if you don't show that one person would be able to start or cease smoking in disseminating awareness of these consequences for the other reasons you mentioned, allowing mitigation of the consequences, and, as you said, planning for them in terms of changing lifestyle choices. And I think you mentioned it would also be preparing in whatever ways people prepare. I took that to be an allusion to planning, financial planning, family planning, whatever, for the consequences. That's the argument the government is presenting here?

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MR. BAER: That's certainly a part of the argument. I would say that, in terms of the planning that I was alluding to a moment ago, I think it is broader than the sort of financial consequences. I sort of meant it not to get too philosophical, but on a more fundamental level of just sort of understanding in that sort of psychological way that "this is what may well happen to me because of this choice," and not feeling blind-sided when it comes about.

Again, I should note and say that for all of these sort of ways in which individuals could imagine using this information, I'm not trying to suggest that we are sort of encompassing the full universe of ways in which information is

valuable. I'm sort of trying to provide the intuitive underpinnings for why we tend to think that that information is valuable; why it's important that individuals be able to make informed choices and why that interest exists if we were to be certain that they wouldn't change their behavior.

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But to be clear, of course, facilitating the ability to change behavior and providing -- arming individuals with information that can allow them to choose a different course is a core part of the value of the information that's being presented here; and so, in that sense, I don't know that it's distinct from the informed consent requirements for surgery. Because, while, yes, people may choose not to undergo surgery, and that's part of the value why we think informed consent is important, because it allows them that choice, my argument is simply, in the informed consent context, we don't need to predict the extent to which individuals will or will not choose to have the surgery based on the information because we still think there's an inherent value to them being fully informed before they make the choice, and it's the same thing here.

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THE COURT: Right. That argument goes to the question of what can count as a substantial interest. And then, of course, *Zauderer* still does have the unduly burdensome argument.

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And to continue the comparison, in the informed consent to surgery context, at least as far as I'm aware, it's not

typical to see large overwhelming parts of marketing materials for waiver or anything like that have graphic depictions of negative health consequences that could result. Whereas, here, the rule requires the top 50 percent of the front and back of all cigarette packages to have the graphics and textual warnings.

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The Seventh Circuit in *Blagojevich* held that a four-inch square sticker was not narrowly tailored because it covered a substantial portion of the box. How is this any less burdensome than the sticker at issue there?

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MR. BAER: So let me take each example in that question in turn, Your Honor, if I may.

Starting with the informed consent context, I actually think that's a very useful example. Because, of course, there, while advertisements for the procedures may not contain the sort of large warning, the informed consent takes place via a conversation with a medical professional. And if before someone purchased each pack of cigarettes, they had to have a conversation with a medical professional about the risks of purchasing that product and consuming it, then I think there would be a much stronger argument that these warnings are not necessarily. Or similarly, if people purchased surgeries behind the counter of a convenience store, I think it absolutely would be likely justified that the consequences of those surgeries be depicted in clear terms that people paid

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attention to and understood.

Whereas, turning to the Seventh Circuit example, where you had a four-square inch label or disclosure on video game labels, there, the principal difference is the court was applying strict scrutiny. This gets to the question of whether information is purely factual or uncontroversial versus whether it's a form of speech, compelled speech that requires some level of heightened. There, because 18 was the label designed to signal that material is sexually explicit, the court conducted an exhaustive analysis there of why that sort of determination, that finding, was an inherently subjective judgment, not purely factual and uncontroversial. And, therefore, any requirement that it be disclosed or appended to a product had to be justified according -- in accordance with the provision for scrutiny, including, of course, strict scrutiny and the narrowed tailing requirement.

So I think the biggest difference is -- there are other differences, but I think the most significant one is the court was using a different analytical lens than should be used here.

11:35AM THE COURT: Let me ask this, which is a question about the limits of your position. On footnote 26 of the District of the DC's 2011 decision, where the court raised the issue of what limits on fast food packaging or labeling would be permissible under this theory, and focused on the burdensomeness aspect of the *Zauderer* test.

As you know, a number of years ago, the government required that fast food restaurants display calorie counts for fast food. And, nonetheless, the National Institute For Health has found that the obesity epidemic continues in the United States.

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So given those findings, would your theory allow some component of HHS to require that fast food packages display a graphic warning tacking up 50 percent of the wrapping or containers for fast food with a picture, the same picture that's present here, about Type 2 diabetes raising blood sugar and someone doing a blood prick test, would that be justified on your view as not unduly burdensome, on giving an argument that increasing awareness of this consequence is still required given the continuing need and the inadequacy, in your view, of higher, more linear labels?

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MR. BAER: So, Your Honor, I think that's a difficult question to answer in the abstract because any such disclosure requirements can only be constitutional in light of the record that exists. And as I sort of noted a number of frames ago in our conversation with Your Honor, the record that we have here includes decades of congressional findings -- or of congressional efforts as well as findings about the evolution of warnings on tobacco labels, and it also includes findings about lack of knowledge about specific health consequences, and findings about the efficacy of certain types of warnings in a

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context of cigarette health warnings. In other words, some of the evidence in the record pertains specifically to what nature and size warnings about cigarettes are most effective at promoting understanding.

11:37AM THE COURT: So your answer is sort of -- just to summarize, your answer is sort of potentially, depending on the record.

MR. BAER: Yes, though it's certainly much harder for me to imagine any time in the near future that sort of record

11:38AM being able to be compiled, if only because we don't have the same length or degree of regulatory tension.

And I would also just note that, at sort of a high level of abstraction, I understand -- I should say, I don't understand there to be any bases -- there is not any safe usage

11:38AM of cigarettes, and I don't understand that categorical statement to be as true in the fast food context.

So, again, there are any number of reasons why I could imagine regulators coming to a different decision about what use is appropriate or necessary to warn about in that context.

11:38AM THE COURT: As part of that answer, you mentioned the findings here about past this information. Let me use that as a transition point to ask you about a Fifth Circuit case, the Fifth Circuit's 2011 decision in the Louisiana Disciplinary Board, which seems to instruct the Court to begin its inquiry

11:39AM by classifying the regulated speech as either deceptive,

potentially deceptive, or not deceptive. That framework does not seem to encompass past disinformation, unless the regulation in question stamps out ongoing potentially deceptive practices.

11:39AM So does the Louisiana Disciplinary Board allow this Court to consider past deception as part of classifying the speech regulation in question?

MR. BAER: So, candidly, Your Honor, I'm not familiar with the specifics of Louisiana Disciplinary Board as you're 11:39AM setting it out.

I will just note that, at least in terms of my initial reaction, that classification is consistent with my understanding of how courts often apply *Central Hudson* in terms of thinking about which -- the sort of steps of *Central Hudson*, 11:40AM and whether something is inherently misleading, then it's something that is not subject to First Amendment protection; and only if it's potentially misleading can there be restrictions on the speech.

And so my initial instinct is that that framework makes 11:40AM no sense in thinking about speech that the government can restrict or prohibit rather than in sort of a disclosure requirement context, because, again, as we've discussed previously, I don't think that the *Zauderer* test can only be geared towards instances of correcting for deception.

11:40AM THE COURT: Let me ask you to provide any concluding

argument on the First Amendment issue, and then turn briefly to the APA Administrative Procedure Act issue.

MR. BAER: So, Your Honor, I think we've covered most of the bases on the First Amendment; but to sort of highlight, I think, some of the key points.

Here, the warnings are purely factual and uncontroversial because they are medically accurate depictions of -- or medically accurate depictions of the health conditions addressed in the warnings as they are typically experienced.

11:41AM THE COURT: I didn't go there with my questions, but since you brought it up. The image of neck cancer, even if a neck cancer might look like that, is a neck cancer far beyond where most neck cancers would be typically be caught and addressed; correct?

11:41AM MR. BAER: So it may well be true that the majority of individuals who suffer from neck cancer would receive treatment before the tumor as depicted in that image is removed.

THE COURT: Is it medically accurate, your hill to die on here? There's picture of a man sitting on a bed. That's

11:42AM not really a medical depiction of erectile dysfunction. Why are you choosing to emphasize that?

MR. BAER: I think you're right, that it is not the hill to die on here. I think it is an important feature of the warnings. That they were developed in consultation with a

11:42AM certified medical illustrator, and that they were designed to

depict, sort of devoid of extraneous context or information, the particular specific health conditions addressed in the warnings.

And the reason why that was the effort or the undertaking is -- again, as I understand it, undisputed evidence in the record -- that cigarette health warnings that combine text and images are better at promoting understanding. The FDA in the rule pointed to a robust body of findings in literature showing that cigarette health warnings that combined images and text promote understanding of the negative health consequences of smoking. And so, there, you have both the concepts that images enhance the message that the text conveys and helps ensure that it gets noticed and comprehended. And so, again, sort of -- we've already discussed why images are valuable for individuals who may not be able to speak the language or read the language that the text is written in. But for the majority of individuals who would be reading or observing these warnings who can both read the text and see the images, for them, it improves understanding to have a supported image linked to the text.

I think the only sort of last point I would make on the purely factual and uncontroversial prong of the inquiry just goes to the question of emotion, because plaintiffs consistently talk about how these warnings may be perceived by the public and whether individuals may have an emotional

reaction to them. But I think even in the colloquy with Mr. Watson that Your Honor had earlier this morning, there was sort of a recognition that when you're dealing with particularly dangerous substances or products, that even a
11:44AM factual statement of the risk can, of course, provoke an emotional reaction. It is a factual statement that tobacco smoke can harm your children. Telling that to a parent may provoke an emotional reaction because no one wants to think that their actions are harming their children. But that
11:44AM doesn't render the ensuing warning any less factual or render it controversial, just because the stakes are so high.

And I think that is why plaintiffs spent so much time focusing on the emotional reaction, rather than really getting at FDA's intent. And the sort of language from RJ Reynolds I
11:45AM from the DC Circuit's 2012 decision that plaintiff highlights, by contrast, does place the focus on the agency's intent if the presence -- or in terms of whether or not an emotional reaction is something that should cause a court any First Amendment concerns. That sort of trying to convey the subjective values
11:45AM or judgments, one way that you might be able to tell that the government is doing that is that the government is just trying to evoke an emotional reaction rather than to convey purely factual and uncontroversial information.

So I, respectfully, don't think this is a useful metric
11:45AM in determining whether these warnings fit into the purely

factual and uncontroversial part of the *Zauderer* analysis to ask, well, do people have emotional reactions to learning information about the dangers of cigarette smoking. I think, as we noted in our brief, that's more likely to be a reaction to the dangers of smoking than it is to anything that is unfactual or controversial about the warnings that the FDA has selected here.

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THE COURT: If you could just briefly turn to your notice and comment and arbitrary and capricious and to the plaintiff's challenges on those grounds, and specifically talk about why did FDA withhold the qualitative study reports, and should the Court be concerned that interested parties had only 15 days to comment on the multi-hundred page documents?

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MR. BAER: So, Your Honor, starting with the second part of that inquiry, the answer is no, I don't think the Court should be concerned that interested parties had 15 days to comment on, I believe it was a total of four documents totalling less than 600 pages, when they had four times that time for well more, and four times that volume of information for the entirety of the information that was on the public document.

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And I respectfully suggest that, if anything, having a targeted 15-day period for just these four qualitative study reports likely allowed them to receive even more attention in the docket then they may otherwise have received if they were

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up along with every other piece of information that was available during the rule making docket for the 60-day period.

Therefore -- sorry, I didn't mean to interrupt Your Honor.

11:47AM THE COURT: Please, go ahead.

MR. BAER: Of course, here, as we note in our brief, the case law that the plaintiffs cite that suggest that this period is inappropriate or is somehow insufficient pertained to comment period at large for the entire rule making; not the

11:48AM sort of supplemental period that is focused on a specific subset of information, as happened here.

Moreover, I would note -- and this sort of leads naturally into the point that even if Your Honor were to agree that that period wasn't sufficient under the APA, I think it

11:48AM would certainly still be subject to the harmless error argument because plaintiffs have not shown substantial prejudice from having 15 days to comment, as evidenced by their argument here, which rely on and reflect the same characterization of those qualitative study reports for the comment period. There's

11:49AM nothing material to their advocacy and certainly nothing that would suggest the underlying decision the FDA made would change if they had been given more than 15 days to comment on these four reports.

THE COURT: Well, the plaintiffs note a memo to file

11:49AM included in the administrative record where the FDA explained

that it did not disclose some of the raw data in question because doing so would allow third parties to analyze the data differently and in ways other than what FDA prespecified. Your footnote responding to that point called it irrelevant.

11:49AM But isn't allowing interested parties to comment on potential different readings of data one of the core purposes of notice and comment procedure?

MR. BAER: So giving interested parties the opportunity to comment on the substance of the proposed rule where a

11:50AM description of the subject and issues involved is the touchstone of the notice and comment period, and that language comes from the APA itself at 5 USC 553(b)(3).

But, here, the agency more than satisfied that obligation through providing the text of the study reports,

11:50AM which in exhaustive detail walked through how the studies were conducted, the justification for the measures that the agency selected, and an analysis of the results and findings; and I think, in terms of providing the ability to comment that the APA provides, providing those study reports.

11:51AM And I would just note that the quantitative study reports were part of the initial rule making docket. And, there, that was because they were sort of central to the rule making undertaking rather than sort of ancillary developmental parts of the process.

11:51AM Having the opportunity to review and comment on those, I

think, was more than sufficient, as evidenced by the fact that although plaintiffs suggest that being denied the raw study data from the quantitative study reports prejudices them, they don't actually cite any of the raw study data, any of the raw quantitative study data in their briefing. They attach it, what they describe as a second appendix, that includes quotes from qualitative studies, but I don't understand them to be using those quotes in a manner that is materially different from how they used the qualitative study reports, which accurately summarized and previewed many of the quotes that they have excerpted from the qualitative study transcript themselves.

But then, on the quantitative study raw data, there's just nothing from plaintiffs. And so, certainly, there, they have not carried their burden to demonstrate that any error wasn't harmless.

But, again, as we were discussing a moment ago, I don't think there was any error here, given the level of detail that was provided in the reports, which I think is what distinguishes this case from others where a lack of data has been cited as a reason that an agency didn't comply with the notice and comment requirement.

We cite in our brief the Fifth Circuit's *Chemical Manufacturers Association* case. And, there, you had a situation in which the EPA withheld -- not to violate the

notice and comment requirement even though it didn't provide the data from an economic impact study that it used, because it had appropriately disclosed the method the EPA followed -- the data it proposed to rely on and its intention to develop an economic impact study but then didn't disclose the ultimate data it did rely on, and the Fifth Circuit found that that wasn't a notice and comment violation. And I think the same reasoning applies, of course, here, where, given plaintiffs and other members of public were given adequate notice of how the studies were being conducted and what the FDA had found, that that's sufficient to have allowed all of the comments that the agency, of course, did receive, and to allow the arguments that have been repeated in the litigation here.

Your Honor, you'd mentioned --

THE COURT: Go ahead and wrap up.

MR. BAER: I would just briefly like to touch on the other APA argument that Mr. Watson dealt with explicitly, which is just a question of the cost benefit analysis and whether the agency conducted an adequate one. I think this argument is addressed sufficiently in the briefs.

I would just note that the plaintiff's briefing and in argument today, it still has not mentioned the *Nicopure Lab* case from the DDC at 266 F.Supp.3d 360, where, at page 406, the court considered exactly this argument, the question of whether FDA specifically was entitled to use a break-even approach in

its cost benefit analysis. And, there, the court highlighted that there was, quote: No statutory duty to quantify the benefits at all; and that even if such a duty could be implied, there's no requirement that the -- sorry -- that there was no
11:55AM requirement that the benefit be quantified in any particular way when compared to the cost.

So, here, there's no argument that plaintiffs have raised that the agency was required under the Tobacco Control Act to conduct a particular form of cost benefit analysis. In
11:55AM the final regulatory impact analysis, the agency explained why the particular benefit at issue in this rule that the agency was pursuing -- mainly, this sort of public understanding benefit that we've been discussing -- are difficult to monetize and to quantify.

11:55AM And so, there, the purpose of a cost benefit analysis is to distil the trade-offs at issue for a decision maker, providing a break-even approach that says: This rule equals and benefits the monetary amount of the cost if you ascribe one nth of value to each cigarette package that contains the
11:56AM disclosure. I think that framing was certainly permissible and well within the bounds of the APA.

THE COURT: When the government issued rules requiring disclosure of calorie counts at fast food restaurants, or, for that matter, on cereal boxes and other items of food, did it
11:56AM conduct a cost benefit analysis of any sort or purport to

analyze whether the disclosure of that information would lead to fewer calories consumed?

MR. BAER: Candidly, Your Honor, I'm not sure, one way or the other.

11:56AM THE COURT: Just on remedy, quickly, you argue severability. Hypothetically, if it were the case that the graphic component of these labels is what lead them to fail, first, administrative scrutiny, how could they be severed and the rest the rule be maintained?

11:57AM Presumably, the 50 percent requirement was tied to the graphics, so that would presumably have to be struck down, again, hypothetically, assuming that what made them unduly burdensome was the graphics. So how would the rule operate, on your view of severability and assuming my hypothetically stated

11:57AM view of the merits?

MR. BAER: So, Your Honor, I would say two things to that. And the first may cite part of that hypothetical, but then the second will attempt not to so cite.

First is I think if you were to strike just the images,

11:57AM then the rest of the rule would still sort of function and make sense as a whole and would go into effect. And by that I mean the statutory requirements as to size exist independent of the requirement that there be graphics included, and therefore the size requirements and the textual warning statements that the

11:58AM FDA issued and assessed and determined to promote understanding

of the negative health consequences of smoking better than the false statements of the EPA. Those statements emphasized, as specified in the statute, would go into effect. And so I think that would be a very clean way, if Your Honor were to decide that the rule needs to be severed, to do so.

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And, of course that specific possibility was contemplated by the agency in the text of the final rule here. This is a case where you have extraordinarily clear congressional and agency commands regarding severability, and the agency specifically considered the possibility of all the images being severed.

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If Your Honor were to conclude that both the size and the image requirements are invalid and need to be severed, then I think the remaining textual warning requirements would go into effect, and I guess it would depend a little bit on the nature of Your Honor's ultimate opinion of sort of how exactly that would operate or function. And I sort of respectfully suggest that if it were to get to that particular point or decision note, perhaps the best way to address the issue would be through sort of supplemental briefing.

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But for the reasons we've been discussing, I don't think we need to get to that contingency.

THE COURT: One final question, which is a little bit imprecise but broadly falls under the category of: Is there anything else like this?

11:59AM

And a more precise formulation would perhaps be: Can you provide citations to any other product or service labeling warning requirement in this country's history that is like -- not in the sense that it precludes a graphic, because I
12:00PM understand the skull and crossbones on poisoning is graphical in that sense -- but in the sense that it takes up half of any one surface of the wrapping or advertising for that product, and includes images that are expressly designed to sort of communicate starkly the negative health consequences of the
12:00PM product or service? Is this the first warning requirement that meets those parameters in the country's history, or am I unaware of some other?

MR. BAER: To my knowledge, Your Honor, this is the first time that these kinds of warnings have been developed and
12:00PM used.

And I think the sort of intuition for why that makes sense is, first, just the nature of the product. Just as Your Honor's unaware of warnings that look like these, I'm unaware of a consumer product that poses the magnitude and variety of
12:01PM risks that cigarettes do.

THE COURT: How about opioids?

MR. BAER: So, there, opioids are prescription drugs. And consistent with the conversation we were having earlier about Your Honor's hypothetical regarding surgery, there's a
12:01PM conversation with a prescriber. If opioids were available --

and, here, I'm going to turn a little outside of my knowledge, so I apologize if I misstate any of the sort of relevant sale restrictions -- but if opioids were available with the same degree of ease as cigarettes, and there had been a history of
12:01PM insufficient warnings, promoting --

THE COURT: Well, based on the epidemic in this country, one could argue that they are so available.

MR. BAER: Respectfully, Your Honor, although the -- by no means do I wish to downplay the severity of the scale of the
12:02PM opioid epidemic. I don't think even taking, given how significant that epidemic is, it would be fair to say that those are as available as cigarettes are. One can't go to a convenience store counter and, you know, no questions asked, purchase opioids. And I think if one could, then the question
12:02PM of whether these sorts of warnings would be justified.

That strikes me as potentially a close question and perhaps a situation where you might also end up with this kind of warning, again, given the magnitude of the risks and of the harm.

12:02PM THE COURT: And I don't mean to venture too far down that trail. My primary question was just a factual one, to make sure that I was not missing something in understanding that this is the first time to see warnings that are like these insofar as meeting the parameters that I've described. So
12:03PM thank you for your help with that.

I think we've drawn enough attention to my questions for the defendants. I want to know if either of the parties would like another short recess for comfort at this point.

I would like to offer the plaintiffs a chance to respond to the government's arguments, and then we'll wrap up. Does either party request a short recess?

MR. WATSON: Your Honor, this is Mr. Watson. I would appreciate the opportunity for rebuttal.

I'm happy to take a recess or to keep going, whatever is more convenient for the Court and for Mr. Baer.

THE COURT: Not hearing that you request one, Mr. Baer, are you content to continue without a recess?

MR. BAER: I am, Your Honor. Though, likewise, defer to the Court and to Mr. Watson.

THE COURT: Well, then, let's just continue.

Mr. Watson, I'd like to give you the opportunity to respond to any of the government's arguments this morning.

MR. WATSON: Thank you, Your Honor. I'd like to just quickly circle back to a few of the issues that have been discussed this morning.

First, with respect to the hypothetical possibility of severing to include text only warnings, I'd like to note three quick things.

First, that would still be unduly burdensome. In *American Beverage*, the Ninth Circuit, en banc, recently

invalidated under *Zauderer* a text only requirement that applied to just 20 percent of the ads, which is far less burdensome than the warnings here. Here, the government hasn't even tried to justify including on the front and the back.

12:04PM Secondly, the government's main study didn't even test whether a text only warning of any size, let alone on both sides of the package, would materially advance any interest, so the government hasn't carried its burden to justify text only warnings here.

12:05PM Third, on a practical note, this would take a long time to implement, and the cigarette manufacturers would need the full 15 months because they would have to start from scratch in redesigning the packages and the like.

Now, as to the value of the information in the

12:05PM warnings -- even the government concedes, at page 14 of its reply brief, that the information must have value; and it said here, today, that they must put up or shut up. But they have not put up.

And two quick points on that front.

12:05PM In addition to the points I made in my principal argument, it's important to note that Dr. Klick found, by analyzing FDA's own data, that acquiring knowledge of the risks addressed in these warnings would have zero effect on smoking and would generally have no effect even on people's assessment

12:05PM of the risks of smoking. And FDA doesn't actually know the

informational value because it doesn't know what message the public is receiving. It didn't test that. The new information on which they hang their hat largely on didn't reveal which message or health affects the viewers took away from the warning; and, indeed, they could have taking away a misleading or inaccurate message.

Just to give an example, the head and neck cancer warning that Your Honor referred to suggests that head and neck cancer always occur from smoking and that it often results in a lump of that size. And that is misleading because the government, even on its own terms, is saying, well, that would be true if the person didn't have access to medical care, which is an issue not addressed in those warnings.

There was discussion in both parties' arguments about the *Warren-Lambert* case. And I would just like to point out that in over 100 pages of briefing by the government, they never cite that case.

Mr. Baer noted also that there have been years of effort by Congress and others to address these issues. In response, I would say that such efforts have been sufficiently effective in informing consumers; they just haven't completely gotten all consumers to quit. So the FDA is now attempting to compel antismoking advocacy, pure and simple, which would get strict scrutiny review. In any event, it's an antismoking advocacy that has no effect in reducing smoking. FDA couldn't show that

in 2011. They didn't try to show it now. We put in expert evidence based on FDA'S data showing that it won't occur now.

As to the discussion about causal language, in discussing the word "causes," just to clarify, we're not saying that there is no correlation between smoking and various health consequences. What we're saying is that the use of the word "causes" goes beyond that, and was misleading about the risk. And, again, FDA's own study showed that this language was problematic. It was the most prevalent finding in FDA'S study.

12:07PM Mr. Baer also pointed to the dictum from the *NIFLA* case where the court included a caveat at page 2,376, that that court doesn't, quote: Question the legality of health and safety warnings long considered permissible, unquote.

But I think there are three reasons why that one 12:08PM sentence of dictum doesn't get the government anywhere in this case.

The first is *NIFLA* doesn't say whether *Zauderer* applies to these traditional warnings; it only says that they are permissible. So it's not even addressing the *Zauderer* question 12:08PM for which the government pointed to this dictum.

Secondly, even if *Zauderer* applies to those traditional warnings, the court provides no definition of what a health and safety warning is. And the definition surely can't include all warnings touching on health and safety considerations, because, 12:08PM most pointedly, that caveat by the *NIFLA* court didn't protect

the licensed notice that was at issue in *NIFLA* even though, as the dissent in that case noted, the relevant statute was justified, in part, by health and safety consideration.

And the third of the three reasons why this dictum in *NIFLA* is unavailing here is that it is undisputed that these graphic warnings are unprecedented. They're not traditional warnings long considered permissible. The types of image, the size and burdensome nature of these warnings, is unprecedented, as the government even conceded today. So they certainly aren't warnings that have long been considered permissible.

We also addressed the skull and crossbones hypothetical in several respects, and I just wanted to note that an additional difference between the skull and crossbones and the warnings we have here is that skull and crossbones might potentially be okay for a poison warning where there's a risk of immediate death in most cases, but that's a different question than warnings for products whose long-term use may have health consequences. So it's a bit of an apples and oranges in that respect.

Just two final points. When we discussed preclusion earlier, I just wanted to clarify that the preclusion issue is only even relevant to the question of our constitutional challenge to the TCA warnings provision. That's what was at issue in *Discount Tobacco*. And, of course, for all the reasons I said, preclusion doesn't apply here. But I just wanted to

clarify that the scope of that discussion is limited to our constitutional challenge to the statute.

And then my final point is just that the implications of the government's theory here are unprecedented and are far-reaching. If the government's view is correct, then *Zauderer* review would apply to things such as pictures of diseased feet on fast food bags, pictures of mutilated cows on packages of beef, and things of that nature. That cannot be right. It's not only inconsistent with precedent and with RJR, but it is inconsistent with First Amendment, first principles.

THE COURT: Very good. Thank you, Mr. Watson.

And given your engaged colloquy with the Court this morning, I don't have any more questions for you on reply. Thank you for your reply arguments.

Mr. Baer, for the government, if you would like to take one minute or two minutes to respond to anything in the plaintiff's reply only, you have that time now.

MR. BAER: Your Honor, we've had a lengthy conversation this afternoon -- or what is now this afternoon -- so I don't need to take up much more of the Court's time.

I would just note one particular thing that I felt was interesting that Mr. Watson said in his reply, which just concerns the skull and crossbones image. He said that would be more appropriate in cases of immediate threat or risk of death than something like cigarettes that has a more long-term time

horizon in which it causes distinctive health affects. All I would note there is, of course, the suggestion that that image is appropriate in different contexts just reinforces the extent to which plaintiff's framework for thinking that any image that has multiple connotations can never be appropriate. That framework can't be right if Mr. Watson's sort of parsing of immediate versus long-term death for skull and crossbones images is correct because that implies, of course, an engagement with an image and assessing a time horizon from an image and all of these ways in which individuals have to subjectively interact with an image. And, of course, that's part of any communication, whether via image or via text. And I just think it's interesting to note that the place for which plaintiffs are comfortable sort of resting on acceptable images in this case is an abstract one that is, of course, subject to interpretation, but one that we all recognize intuitively falls well within the bounds of what purely factual and uncontroversial information includes. So I think that sort of concession and that use of that image as kind of the prime example on the part of plaintiffs just reinforces why there's a much wider range of acceptable images that exist and are available for the government to use than the plaintiffs had been otherwise willing to acknowledge or recognize.

THE COURT: Let me thank the parties for their flexibility in accommodating the telephonic nature of today's

hearing and for the responsiveness to the Court's questions. I believe I have a better understanding of your positions as a result, and I thank you for that.

With that, this hearing is adjourned, and the motions 12:13PM will remain under submission. Thank you.

MR. WATSON: Thank you, Your Honor.

MR. BAER: Thank you, Your Honor.

MR. PERRY: Thank you, Your Honor.

[PROCEEDINGS CONCLUDED]

OFFICIAL COURT REPORTER'S CERTIFICATE

I (we) certify that the foregoing is a correct transcript of proceedings in the above-entitled matter.

/S/ Susan A. Zielie, RMR, FCRR

Susan A. Zielie, RMR, FCRR
December 27, 2020